IVAC
MEDICAL SYSTEMS™

Directions for Use

I

[redacted]

IVAC
MEDICAL SYSTEMS™

Patient Controlled Analgesia Pump

Model P5000

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Please read this operators manual carefully before using this IVAC instrument for the first time and then retain it for future reference. It is the responsibility of the user to follow the instructions and recommendations contained herein.

Manufactured by: IVAC MEDICAL SYSTEMS, Unit 2 Beechwood, Chineham Business Park, Chineham, Basingstoke, Hampshire, RG24 8WA.

Part No. 5301FAGPT21 (Issue 5) IVAC and PCAM are trademarks owned by IVAC Medical Systems Limited in England (1.02.97)

GENERAL AND PATIENT PRECAUTIONS

This **IVAC™** instrument is calibrated for use with single use disposable syringes of nominated make and size. To ensure correct and accurate operation, only use the luer lock version of the syringe make and size specified on the pump display and an extension line suitable for the administration of PCA on a syringe pump. Use of non-specified syringes may impair the operation of this unit and the accuracy of the infusion.

Uncontrolled flow may result if the syringe is located on the unit without its finger grips and plunger correctly restrained in the slots provided, or if it is removed from the pump before the extension line is properly isolated from the patient access device, for example, by clamping the extension line or closing the appropriate tap.

When combining several apparatuses and/or instruments with administration sets and other tubing's, for example via a 3-way tap, the performance of the pump may be impacted and should be monitored closely.

Do not mount the pump in a vertical position with the AC power inlet or syringe pointing upwards as this could effect electrical safety in the event of a fluid spill over the unit or lead to the infusion of air which may be in the syringe. To protect against the introduction of air, the user should regularly monitor the progress of the infusion, syringe, extension line and patient connections and follow the priming procedures specified herein.

This is a positive pressure device designed to achieve very accurate fluid administration by automatically compensating for the resistance encountered in the infusion system, for example due to a small bore cannula, in-line filters, micro bore extension lines, high flow rates, viscous fluids etc.

The pumping pressure alarm system is not designed to provide protection against, or detection of, infiltration conditions which can occur at low pressures.

Several alarm conditions detected by this pump will stop the infusion and generate audible and visual alarms. Users must perform regular checks to ensure that the infusion is progressing correctly and no alarms are operating.

An explosion hazard exists if this instrument is used in the presence of flammable anaesthetics. Exercise care to locate the unit away from any such hazardous sources. An electrical shock hazard exists if the instrument casing is opened or removed. Refer all servicing to qualified service personnel.

This instrument is protected against the effects of external interference, including high energy radio frequency emissions, magnetic fields and electrostatic discharge (for example as generated by electrosurgical and cauterizing equipment, large motors, portable radios, cellular telephones etc.) and is designed to fail safe if unreasonable levels of interference are encountered.

In some circumstances the unit may be affected by electromagnetic interference of field strength less than 10V/m and electrostatic discharge of less than 15kV. If the unit is affected by this external interference the unit will fail-safe or reset (a call back alarm will occur after 2 minutes). Should false alarm conditions be encountered either, remove the source of the interference, or, regulate the infusion by another appropriate means.

If this instrument is dropped, subjected to excessive moisture, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by a qualified service engineer. A comprehensive service manual containing circuit descriptions, servicing and testing information is available for this instrument. It may be ordered from **IVAC**, or your authorised **IVAC** distributor. **(Service Manual Reference 5000PB00004).**

SPECIFICATION

	IVAC PCAM - Model P5000	
CONCENTRATION RANGE	1ug/ml - 999ug/ml in 1ug/ml steps 0.1mg/ml - 99.9mg/ml in 0.1mg/ml steps	
PCA DOSE RANGE	Mass Mode: 0.0ug - 999ug in 1ug steps 1mg - 99.9ml in 0.1mg steps Volume Mode: 0.0ml - 99.9ml in 0.1ml steps	
PCA DELIVERY RATE	100ml/h max. STAT rate for 30ml, 50ml and 100ml syringes and 80ml/h for 20ml syringes. (Option to set duration from 1 to 60 mins in 1 min steps to minimum rate of 0.1ml/h and maximum of the STAT rate).	
RATE CONVERSION FACTOR	When PCAM is programmed in Mass units the conversion factor is:- ml/h = (dose/concentration)/(time in minutes/60).	
LOCKOUT INTERVAL	0 - 180 minutes in 1 minute steps	
LOADING DOSE RANGE	Mass Mode: 0ug - 999ug in 1ug steps 0.0mg - 99.9mg in 0.1mg steps (Delivered at STAT rate) Volume Mode: 0.0ml - 99.9ml in 0.1ml steps	
CONTINUOUS RATE RANGE	Mass Mode: 0ug/h - 90ug/h in 10ug/h steps 0.0mg/h - 99.9mg/h in 0.1mg/h steps Volume Mode 0.0ml/h - 20.0ml/h in 0.1ml/h steps.	
MAX DOSE LIMIT	Mass Mode: off, 1ug - 999ug in 1ug steps 1mg - 999mg in 1mg steps Volume Mode: off, 0.1ml to 999ml in 0.1mg steps 1 - 8 hours duration in 1 hour steps	
PURGE RATE	100ml/h	
SYSTEM ACCURACY	Drive Linearity: +/- 1% Bolus: +/- 0.05ml Volumetric: +/- 2% (nominal) (Volumetric accuracy is +/-2% typical by volume at the STAT PCA rate and above when the instrument is used with the recommended syringes. Differences in factors such as size and plunger force in compatible syringes can cause variations in accuracy and trumpet curves.)	
OPERATION MODE	Continuous	
CRITICAL VOLUME	The maximum over infusion which can occur in the event of a single fault condition is 0.8ml for 20ml, 30ml and 50ml syringes and 1.5ml for a 100ml syringe.	
ALARM CONDITIONS	Pressure Limit exceeded Drive Disengaged Syringe Almost Empty Syringe Empty Internal Malfunction Nurse Attention/Call Back	Low Battery Warning Battery Exhausted Cover Open during Operation Hand-set Disconnected Syringe Error
PUMPING PRESSURE ALARM LEVEL	375mmHg (nominal) default alarm level with 11 user selectable alarm levels. Syringes may limit below level 10. (The maximum pressure that can be developed by the system at the maximum user selectable alarm level is 1100mmHg).	
CLINICIAN OVER-RIDE	Bolus or continuous infusion in RUN mode. (User selectable from 1ug - 99.9mg or 0.1ml to 99.9ml (volume mode) bolus dose administered at the STAT rate (100ml/h) or over 1 to 180 minutes delivery period). Modify PCA Protocol in SET mode. (When option to disable MODIFY PROTOCOL has been selected)	
BATTERY OPERATION	6 hours operation from a fully charged battery at 5.0ml/h and 20°C under normal conditions.	
BATTERY TYPE AND RECHARGE TIME	Rechargeable sealed lead acid type. 10 hours from discharge to 80% charge, 24 hours from discharge to 100% charge	
EVENT HISTORY	1500 events rolling memory	
MEMORY RETENTION	All calibration and set up information will be retained in the pump memory for a minimum of 3 years.	

SPECIFICATION (continued)

IVAC PCAM - Model P5000

SYRINGE TYPES

	20ml	30ml	50ml	100ml
IVAC			✓	✓
BD Plastipak	✓	✓	✓	
Terumo	✓	✓	✓	
B Braun Omnifix	✓	✓	✓	
Sherwood Monoject	✓	✓	✓	
RR Pronto	✓	✓(35ml)	✓	
BD Worldwide	✓	✓	✓	
Once			✓	
Fresenius Injectomat			✓	
B Braun Perfusor			✓	
Janpol			✓	
Rapiject			✓	

EXTENSION SETS

The unit uses a standard, single use, disposable extension line with luer-lock connectors, of type suitable for the delivery of PCA from a syringe pump. (For example IVAC models 30852 and 30862).

(IVAC recommend the use of a PCA set with an anti-syphon valve at the syringe and a non-return valve at the Y-site (if fitted). If an anti-syphon valve with a high "cracking" pressure is used, it may cause false occlusion alarms and it may be necessary to adjust the pumping pressure alarm level. See General Options.)

AC POWER SUPPLY

220-240VAC, 50/60Hz, 16VA (nominal) - Input fuse T63mA Time Lag (5 x 20mm)

110-120VAC, 50-60Hz, 16VA (nominal) - Input fuse T125mA Time Lag (5 x 20mm)

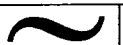
ENVIRONMENTAL

	OPERATING	TRANSPORT/STORAGE
TEMPERATURE	+10°C to +40°C	-40°C to +70°C
RELATIVE HUMIDITY	30% to 75%	10% to 100%
ATMOSPHERIC PRESSURE	700mbar to 1060mbar	500mbar to 1060mbar

SYMBOL DEFINITION AND EQUIPMENT CLASSIFICATION

	Attention, consult accompanying documents.
	Potential Equalisation Connector
	Communications Connector (RS232 or RS485 (optional) connector)
	Patient hand-set connector (Hand-held switch)
	Nurse Call Connector
	Class II equipment. (Internally powered equipment).
	Type CF equipment. (Degree of protection against electrical shock).
IPX4	Protected against splashing water. (Degree of protection against liquid ingress).

SPECIFICATION (continued)

	Alternating current.
0473	Device complies with the requirements of the EC Directive 93/42/EEC. Certified by Amtac Mediqa.
CASE MATERIAL	Polyurethane (with fire retardant)
DIMENSIONS	400mm (w) x 115mm (h) x 180mm (d). Weight: 3.5kg. (excluding pole clamp and power cable)
ELECTRICAL SAFETY	Complies with BS5724 Part 1: 1989, IEC 601-1: 1988, and EN 60601-1:1990.
MANUFACTURER PATENT NOTICE	This instrument is designed and manufactured in the UK by **IVAC MEDICAL SYSTEMS**, Unit 2 Beechwood, Chineham Business Park, Basingstoke, Hants, RG24 8WA under patent GB 2224444.

IVAC Medical Systems reserves the right to alter product specifications without notice.

INTRODUCTION

The **IVAC PCAM** system allows a patient to maintain a consistent level of pain relief by providing self administration of a clinician-prescribed dose of analgesic as and when it is required.

When the hand set is operated and the demand is within the parameters set by the clinician, the **PCAM** will automatically administer a precise bolus dose of analgesic.

For enhanced monitoring and management of post operative acute pain within the hospital, the IVAC **PCAM** provides convenient Patient Controlled Analgesia (PCA) and detailed information at the bed-side about the patients use of PCA.

Central to an effective pain service, **PCAM** promotes improved pain management, more effective use of nursing resources, better patient outcomes and can contribute towards a quicker discharge from hospital. Typical applications for **PCAM** include:-

- **Post Operative Pain Control**
- **Oncology**
- **Labour**
- **Trauma**
- **Orthopaedics**
- **Paediatrics**

IVAC PCAM - Patient Controlled Analgesia Management

Unique features of **PCAM** include:- user configured PCA protocols, two key positions providing separation of nursing and programming procedures, comprehensive history and a unique electronic hand set with status indicator.

As some hospitals use standard protocols for many patients, **PCAM** provides the facility to program up to 5 pre-set hospital PCA protocols. A wide range of parameters including the drug name, the concentration, the PCA bolus dose, the lock out period between doses, background and loading doses can be programmed.

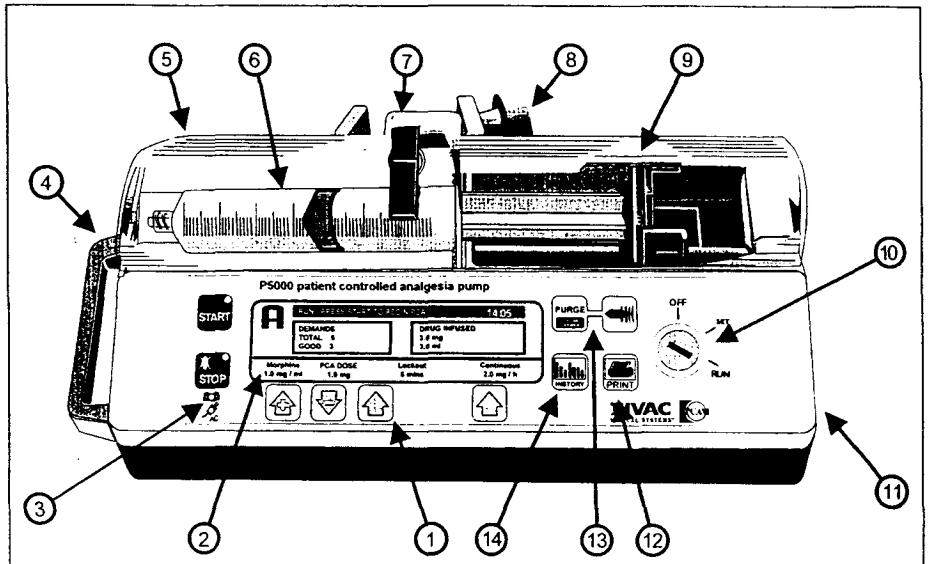
To provide clear separation between nursing and clinical procedures, the **PCAM** system is fitted with two separate key positions. One for routine nursing procedures like changing the syringe and one for clinical activities like switching the unit on and selecting the PCA protocol.

PCAM accommodates a wide range of standard 20ml, 30ml, 50ml and 100ml disposable syringes and can be used with any standard extension set suitable for the administration of PCA from a syringe pump.

IVAC PCAM - PATIENT CONTROLLED ANALGESIA PUMP

The **IVAC PCAM** patient controlled analgesia pump is one of the IVAC family of "P" Series syringe pumps. Many aspects of general operation, performance, accuracy and safety checking systems designed into the **PCAM** unit are common throughout the range.

The system uses a range of standard disposable syringes in various sizes and standard PCA administration sets. The cover is manufactured from very strong polycarbonate and designed to be resistant to breakage and discourage unauthorised access to the syringe.



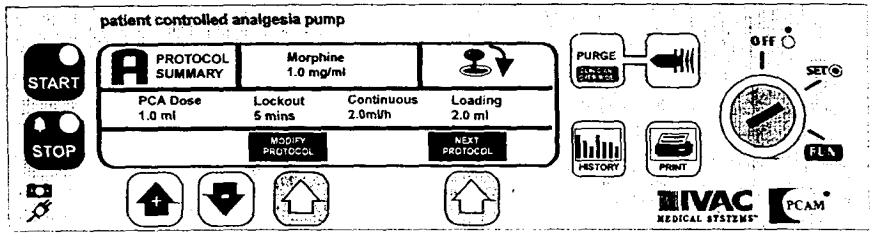
1	Touch panel controls	9	Plunger holder and declutch lever
2	Large illuminated graphics display	10	Front panel key switch
3	AC and battery indicators	11	Patient hand-set, communications and nurse call connectors
4	Key to open cover	12	Print button
5	Strong polycarbonate cover	13	Clinician over-ride and purge buttons
6	Standard disposable syringe	14	History button
7	Syringe clamp		
8	Pole clamp		

CONTROLS, INDICATORS AND DISPLAYS

Touch panel controls provide simple and logical operation and are very easy to clean. For additional security, most controls are disabled while the key switch is in the **RUN** position and the key must be in the **SET** position before any settings can be changed.

After 5 minutes normal operation, a **DISPLAY SLEEP** feature automatically dims the display backlight and the IVAC PCAM logo replaces the PCA protocol. When display sleep is enabled, this mode can also be entered during operation by pressing and holding down the START button for 4 seconds.

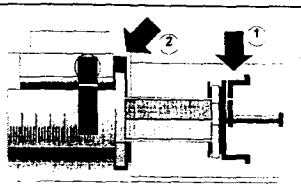
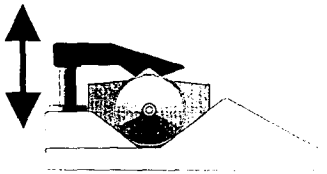
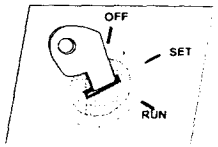
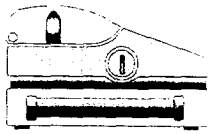
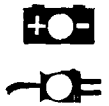
IVAC PCAM FRONT PANEL CONTROLS



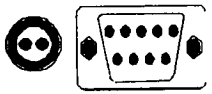
START	Press **START** button to commence **PCAM** operation. The **GREEN** light will illuminate when the pump is infusing.
STOP	Press **STOP** button to stop **PCAM** operation and cancel any alarms. The **AMBER** light will illuminate when the pump is stopped and flash to indicate an alarm.
PURGE	Press both **PURGE** buttons simultaneously and hold down to purge the extension line during set up. **PURGE** will only operate when the cover is open and the key switch is in the **RUN** position.
	Use "+" and "-" arrow buttons to move cursor and increase/decrease values shown in display during in set up and configuration.
	Use **ARROW** buttons in conjunction with prompts shown in the display.
HISTORY	Press **HISTORY** button to display **PCAM** history graphs and event records.
PRINT	Press **PRINT** button to print patient history. A suitable printer must be connected.

CONTROLS, INDICATORS AND DISPLAYS

Identify the following controls and indicators before using this instrument.

	**DECLUTCH LEVER** Squeeze the declutch lever to disengage drive mechanism and allow manual movement of the plunger holder during syringe loading and priming.
	**SYRINGE CLAMP** The syringe clamp is used to secure the syringe and detect the size of syringe being used. The syringe barrel is located in the V-groove then locked into position by the **SYRINGE CLAMP**. To unlock, lift and rotate to left.
	AC POWER INLET The AC Power Inlet is positioned on the right side of the unit. Connect unit to the AC power supply using the AC Power Cable.
	ALARM VOLUME ADJUSTMENT On base of unit. Use screwdriver and rotate to increase, or decrease, the volume of the audible alarm as required.
	**KEY SWITCH**, The **KEY SWITCH** turns the power **ON/OFF** and is used to select **SET** and **RUN** modes. Switching from **RUN** to **SET** modes without first pressing the **STOP** button will automatically stop the infusion.
	**COVER LOCK** The cover lock is located next to the handle. The slam shut design allows unit to be locked without use of the key.
	**BATTERY AND AC POWER INDICATORS** Indicates when the unit is running from its internal battery or connected to the AC power supply with the battery being charged.

CONTROLS, INDICATORS AND DISPLAYS

	**PRINTER, COMMUNICATIONS AND NURSE CALL CONNECTORS** For connecting printer or peripheral equipment. For connection to a nurse call system. (The nurse call contacts are normally open when unit is switched ON and no alarms are functioning).
	HANDSET This is connected to the instrument, and allows the patient to administer the drug by PCA.

IVAC PUMPING PRESSURE MONITORING SYSTEM

PCAM is fitted with the unique **IVAC pumping pressure monitoring system** which constantly monitors the pressure with which syringe is being driven as the infusion is being administered.

If the progress of the infusion is restricted, for example due to a seized syringe, closed tap or blocked cannula, and the pumping pressure reaches the pre-set pumping pressure alarm limit, the pump will automatically stop, alarm and indicate occlusion.

BENEFITS OF THE PRESSURE MONITORING SYSTEM

- **MINIMUM POTENTIAL BOLUS**
- **USER ADJUSTABLE ALARM LEVELS**
- **LOWER PUMPING PRESSURE ALARM LEVELS**
- **PUMPING PRESSURE AND ALARM LEVEL DISPLAY**
- **FASTER ALARMS IN THE EVENT OF AN OCCLUSION**
- **AUTO ADJUSTMENT OF ALARM FOR SMALL SYRINGES**

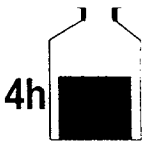
The **IVAC PCAM** pressure monitoring system has been specifically designed for infusions where constant monitoring of the pumping pressure and the ability to set alarm levels appropriate to the individual patient needs are of special importance.

Eleven alternative alarm levels are available from L0 to L10 and indicate increasing pumping pressure alarms in 10 steps of 92mmHg (nominal) from zero up to 920mmHg (nominal). At the highest level, syringes may limit below level 10. The normal default alarm level is level 4 (375mmHg (nominal)).

If higher or lower pumping pressure alarm levels are required, these can be selected by using Modify Protocol within the Set mode. For example, when using PCA extension sets fitted with anti-syphon valves with high "cracking" pressures (sometimes between 100mmHg and 250mmHg), it may be necessary to select a higher alarm level to avoid the possibility of nuisance occlusion alarms.

PUMPING PRESSURE AND MAX DOSE LIMIT "ICONS"

The **PUMPING PRESSURE ICON** can be used provide a constant visual indication of the current pumping pressure and the pressure level at which the alarm will operate. As the pressure required to administer the infusion increases, the box will be filled until the pressure reaches the alarm level, the pump will then stop infusing and the occlusion alarm will operate.



The **MAXIMUM DOSE ICON** provides an indication of the amount of drug that has been administered during the limit period. The limit period is displayed alongside the bottle and the bottle fills up as doses are added to the mass infused. The bottle will appear to be full if the dose limit reaches the alarm level and the pump will then stop infusing and the max. dose exceeded alarm will operate.

Refer to **GENERAL OPTIONS** for instructions for displaying ICONS in the main display.

INSTALLATION

Check that the unit is complete, undamaged and that the voltage rating specified on the base label is compatible with your AC power supply. Items supplied with this IVAC PCAM syringe pump are:-

- ☑ **IVAC PCAM SYRINGE PUMP**
- ☑ **PCAM PATIENT HAND SET**
- ☑ **PCAM KEYS (2)**
- ☑ **POLE CLAMP**
- ☑ **DIRECTIONS FOR USE**
- ☑ **AC POWER CABLE (AS REQUESTED)**
- ☑ **PROTECTIVE PACKING**

Connect the unit to the AC power supply for 24 hours to ensure that the internal battery is fully charged.

Carry out the functional test described in **OPERATION AND ALARM TEST**.

Should the pump fail to perform correctly, replace it in its original protective packing and contact a qualified service engineer for investigation.

If required adjust position of the pole clamp and select special configuration options described in **PCAM CONFIGURATION.**

THE POLE CLAMP

The pole clamp is supplied fitted to the rear of the unit and will provide secure fixing to standard I.V. poles of a diameter of up to 40mm.

The pole clamp can also be fitted in a choice of 4 fixing positions allowing the unit to be mounted to vertical and horizontal poles, equipment rails and hospital furniture in a variety of convenient operating orientations.

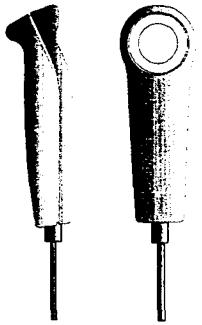
The clamp may be adjusted for use with horizontal fittings by using the existing fixing screws with the alternative fixing holes in the pole clamp.

The pole clamp may also be secured to the base of the unit in a choice of four positions.

IMPORTANT NOTE
DO NOT MOUNT UNIT WITH AC POWER INLET OR SYRINGE POINTING UPWARDS. THIS COULD EFFECT ELECTRICAL SAFETY IN THE EVENT OF A FLUID SPILL OR LEAD TO THE INFUSION OF ANY AIR WHICH MAY BE IN THE SYRINGE.
THE PUMP SHOULD ONLY BE MOUNTED TO A STABLE I.V. POLE, FITTING OR SURFACE WHICH IS DESIGNED, OR SUITABLE, FOR THIS PURPOSE.

PCAM PATIENT HAND SET

The patient hand set supplied with the **PCAM** is designed to be ambidextrous and suitable for both adult and paediatric use. The hand set provides an indicator light which clearly shows when the **PCAM** is available and can be configured to flash when a PCA dose is being delivered.



The indicator on the patient hand set will reflect the configuration of the **PCAM** system and will provide feed-back on all, or just good demands, and the indicator light can be disabled should the clinical situation require

Where appropriate the hand-set can be configured so that the patient will not need to refer to the instrument to assess if PCA is being delivered, or is available.

The hand set is provided with a clip for attaching it to bedding or clothing.

The **PCAM** concept is that the patient can be instructed in the use of the hand set as it will carry all the information required by the patient using PCA. This design simplifies patient instruction and encourage a smooth transfer to alternative devices used to treat long term chronic pain, should this be indicated. Three modes of hand set operation are available:-

PCAM PATIENT HAND SET OPERATING MODES			
MODE	**A**	**B**	**C**
HAND SET BEEP	GOOD DEMANDS ONLY	ALL DEMANDS	ALL DEMANDS
HAND SET INDICATOR:-			
PCAM STOPPED	OFF	OFF	OFF
PCA AVAILABLE	ON	ON	ON
PCA DOSE DELIVERING	"ON-FLASHING"	ON	"ON-FLASHING"
PCA LOCK-OUT PERIOD	OFF	ON	ON

A latching (but non locking) connector makes the hand set easy to fit. To remove, hold the body of the connector and pull away from the pump.

An alarm warning will operate if the hand set is disconnected from the unit while it is in operation or the hand set is connected to the unit with the PCA button depressed. In addition, the unit can be operated in continuous or clinician over-ride modes without the hand set connected, should this be indicated.

OPERATIONAL AND ALARM TEST

Perform this operation and alarm test prior to selecting **CONFIGURATION OPTIONS** and before the pump is used for the first time. This test should be performed periodically to confirm the integrity of the system.

STEP	ACTION	DESCRIPTION
1	SELF TEST	Connect the pump to the AC power supply. Connect the **PATIENT HAND-SET** to the unit. Insert the key in the key switch and turn to the **SET** position. Check for audible alarm and all segments of display are illuminated during the self test routine. **NOTE:-** Key can not be removed from key switch in **SET** position.
2	NEW PATIENT?	Check date and time shown. (See setting the clock if adjustment is required). Press **YES** twice to confirm new patient.
3	PROTOCOL SUMMARY	Check **PROTOCOL SUMMARY A** appears. Press **NEXT PROTOCOL.** Check that protocol **B** appears. Press **MODIFY PROTOCOL**. Check that summary appears. Press - and + arrows in sequence. Check cursor moves. Press **OK**. Check display returns to protocol **B** summary.
4	SWITCH TO RUN	Turn key switch to **RUN** position. Check **CONFIRM PROTOCOL** screen appears. Press **OK**. Check **CONFIRM SYRINGE** flashes.
5	OPEN COVER	Remove key from key switch and place in cover lock by handle. Turn key and check that the cover unlocks. Remove key from lock.
6	SYRINGE SIZE DETECTION	Slowly lift the syringe clamp while pressing in the button sensor in the plunger holder. Check that the **DISPLAY** switches from **"...."** to **"-- --"** then through **20ml, 30ml, 50ml and 100ml.**
7	LOAD SYRINGE	Load a new 50/60ml syringe and extension line filled with water following the instructions given in **OPERATING PROCEDURES**. Press **CHANGE TYPE** until correct make and size of syringe are displayed. Press **OK**.
8	PURGE	Press and hold down the **PURGE** buttons together. Check that unit alarms, the Amber light flashes and the purge rate and volume being primed is displayed. Continue until water flows freely from the extension set. **NOTE:- PURGE** can only be operated with the cover opened and the key switch in the **RUN** position.
9	COVER LOCK	Check **COVER OPEN** is flashing. Push cover to closed position and check that it has locked securely. Check display flashes **START TO BEGIN PCA**.

OPERATIONAL AND ALARM TEST (continued)

STEP	ACTION	DESCRIPTION
10	NURSE ATTENTION ALARM	Wait 2 minutes. Check that the intermittent alarm operates. Press and hold down **STOP** for 2 seconds. After 15 minutes check that alarm operates.
11	START PCAM	Press **START**. Check green **START** indicator light is illuminated and display changes to **PCA AVAILABLE**. Check green indicator light on patient hand set is illuminated.
12	PCA OPERATION	Press button on patient hand set. Check:- Ensure Handset is in A mode • Unit gives an alarm beep. • **PCA INFUSING and % remains** messages are displayed and incrementing volume and drug infused totals. • Green light on hand set begins to flash. Followed by:- • **PCA LOCKOUT** and **minutes remain** message. • Green light on hand set stops flashing.
13	LOCK OUT PERIOD	Observe that the lockout period displayed is reducing and that **PCA AVAILABLE** message is displayed when the lockout period is complete.
14	HISTORY	Press **HISTORY BUTTON**. Check:- • **DEMANDS** shows **PCA** graph for current hour. Press again. • **DRUG INFUSED** shows graph for current hour. Press again. • **HOUR** shows totals by hour. Press again. • **EVENT LOG** shows time, event, and drug total. Press **RETURN** arrow to go back to previous displays to run display.
15	PRINT (OPTIONAL)	If printer is available. Connect and follow instructions in **PRINTING** section.
16	PATIENT HAND SET ALARM	With green **START** light illuminated, disconnect patient hand set. Press **MUTE** to silence alarm but leave message on display. Check **CHECK HAND-SET** message. Reconnect patient hand set and observe display return to normal run display. Press **START** to continue.
17	COVER OPENED ALARM	Insert key in cover lock and open cover. Press **MUTE** to silence alarm. Check **COVER OPENED** message. Close cover and observe display return to normal run display. Press **START** to continue.
18	AC POWER FAILURE	Switch **AC** power supply **OFF** at the wall socket. Check audible alarm and **AC POWER FAIL** message. Switch AC power supply **ON** and the alarm will cancel and pump returns to normal operation.

OPERATIONAL AND ALARM TEST (continued)

STEP/ACTION		DESCRIPTION
	(OPTIONAL)	Performing the following tests can be speeded up by selecting a PCA lock-out period of 0 minutes. To carry this out:- 1. Turn key switch to **SET** position. 2. Press **MODIFY PROTOCOL** button. 3. Use down arrow to select **LOCKOUT PERIOD**. 4. Press **ALTER** button. 5. Press down arrow until lockout period = 0 minutes. 6. Press **CONFIRM** then **OK** to return to Protocol Summary. 7. Turn key switch to **RUN** position. 8. Press **OK** to confirm protocol. (**NOTE:** Lockout period = 0 mins). 9. Press **START** to begin PCA operation
19	**LINE OCCLUSION ALARM**	Occlude the extension set (For example, with a closed three way tap). Press the patient hand-set and give several successful PCA demands until the unit alarms, stops infusing and displays **LINE OCCLUSION**. Press **MUTE** button to silence alarm Remove occlusion in extension set by opening cover and squeezing the declutch lever to remove the pressure in the line. Open the tap. Close the cover. Press **STOP** to clear alarm display. Press **START**.
20	**SYRINGE ALMOST EMPTY**	Press **STOP**. Check **PCA SUSPENDED** message appears. Insert key into cover lock, unlock and open cover. Squeeze the declutch lever and advance the carriage to the left until the 50/60ml syringe reaches the 6.0ml position. Close cover and press **START**. Give a series of successful PCA demands. Check that the unit alarms **NEAR END OF SYRINGE** when it reaches the 3.0ml (+/- 0.5ml) position. Press **START** to silence the alarm.
21	**SYRINGE EMPTY**	Continue to press patient hand-set until unit alarms and displays **SYRINGE EMPTY** message. Press **STOP** to silence alarm.
22	**TEST COMPLETE**	If the unit is not required for use, insert key in key switch and turn to the **OFF** position. Disconnect the unit from the **AC** power supply.

PCAM CONFIGURATION

PCAM can be configured to suit specific clinical needs. Configuration options include:

- **MASS OR VOLUME DOSING**
- **DRUG NAMES AND SAFETY LIMITS**
- **GENERAL OPTIONS**
- **PROTOCOL DEFAULT SET-UP**
- **CLOCK SET-UP**

MASS OR VOLUME DOSING

The standard **PCAM** operating mode is **MASS** dosing where PCA doses are selected in mass of drug (ug or mg). Where indicated, for example when PCA is used by small children, **VOLUME** dosing can be selected where all PCA doses and maximum limits are set in volume (mls).

In volume mode the minimum PCA dose can be selected in increments of 0.1ml. History records and graphs continue to be displayed in Mass. Changing this mode involves entering an access code, see Technician Access Codes.

PCAM PRE-SET PCA PROTOCOLS

If standard protocols are used for the majority of patients, it is possible to configure the unit with a number of pre-set PCA protocols. Up to 5 pre-set **PCAM** protocols can be defined. The protocols are identified with the letters **A** to **E** while a modified protocol has no letter.

The pre-set protocol can be modified by accessing the **SET** mode via the key switch. If the modify protocol option has been disabled in **GENERAL OPTIONS**, the protocol can be adjusted by using the clinician over-ride facility.

Safety limits can be attached to the pre-set DRUG NAMES including maximum and minimum drug concentration and PCA dose so that user modification of a pre-set protocol is automatically kept within a specified range. The following parameters can be selected when defining a pre-set **PCAM** protocol:-

PCAM PRE-SET PCA PROTOCOLS (continued)

	PARAMETER	RANGE/COMMENT
1	DRUG NAME	6 pre-sets plus alpha-numeric entry for 10 characters
2	DRUG CONCENTRATION	1ug/ml to 99.9 mg/ml
3	PCA DOSE	0ug to 99.9mg
4	LOCKOUT PERIOD	0 to 180 minutes in 1 minute steps
5	OCCLUSION LEVEL	L0 - L10
6	CONTINUOUS	Background Infusion
7	LOADING DOSE	Dose to be delivered at the STAT rate. The initial dose is delivered after "NEW PATIENT" is confirmed and the PCA is started.
8	MAX DOSE LIMIT	Max. cumulative dose limit, off ...999mg.
9	LIMIT DURATION	Maximum cumulative period 1 - 8 hours
10	PCA DELIVERY RATE	STAT rate 100ml/h (80ml/h for 20ml syringes) unless the PCA delivery is set to be delivered over a time (1 - 60 mins).

DRUG NAMES AND SAFETY LIMITS

Drug names and safety limits apply to pre-set protocols during protocol selection and modification.

1	Turn key switch to **SET** position while pressing down **START** button.		
2	Enter access code **"2 5 1 "**		
3	Select **DRUG NAMES AND SAFETY LIMITS** from the menu. Press **ENTER**.		
4	**MODIFY DRUG**	Press to modify the drug summary. Use "+" and "-" arrows to select desired values. When field is correct press **OK** to store the selection.	
		Name:	Use "+" and "-" arrows to set highlighted letter. Press **NEXT** for next character (up to 10 letters). Press **OK** when complete.
		MIN CONC:	Use "+" and "-" arrows to set minimum concentration. Press **OK** when complete.
		MAX CONC:	Use "+" and "-" arrows to set maximum concentration. Press **OK** when complete.
		MIN LOCKOUT:	Use "+" and "-" arrows to set minimum lockout period. Press **OK** when complete.
		MAX LOCKOUT:	Use "+" and "-" arrows to set maximum lockout period. Press **OK** when complete.
		MIN DOSE:	Use "+" and "-" arrows to set minimum PCA dose. Press **OK** when complete.
		MAX DOSE:	Use "+" and "-" arrows to set maximum PCA dose. Press **OK** when complete.
		MAX CONTINUOUS:	Use "+" and "-" arrows to set maximum continuous rate. Press **OK** when complete.
		MAX LOADING:	Use "+" and "-" arrows to set maximum loading dose. Press **OK** when complete.
5	**NEXT DRUG**	Press to display the next drug name and safety limits. The five pre-set drug protocols are identified as 1 to 5	
6	**QUIT**	Press **QUIT** to exit and return to configuration menu	

DRUG NAMES AND SAFETY LIMITS (continued)

7	**TURN PCAM OFF**	When set-up is complete, turn key switch to **OFF** position to save selection.
8	**IMPORTANT:** If no specific drug is being used within a protocol, the name **"DRUG 1, 2 etc."** will appear in the protocol summary as a heading for the drug concentration in use. In addition, the name **"DRUG CONC."** can also be selected from the standard drug name menu available in the protocol set-up and modification modes.	

GENERAL OPTIONS

General options allow **PCAM** to be configured to suit the specific requirements of a particular clinical situation. The selected should be recorded on **the CONFIGURATION RECORD SHEET** for reference.

1	Turn key switch to **SET** position while pressing down **START** button.	
2	Enter access code **"2 5 1".**	
3	Select **GENERAL OPTIONS.** Press **ENTER**. Use **"+"** and **"-" ARROWS** to select values/options, **NEXT** to move to next option and **QUIT** to return to menu.	
	1. ICONS on display	**YES** - displays pumping pressure and 4 hour limit ICONS. **NO** - ICONS disabled.
	2. Protocols in use	PCA pre-set protocols to be available. Select number from 1 to 5.
	3. Modify protocol	**YES** - allows protocols to be modified in SET mode. **NO** - removes modify protocol option in SET mode.
	4. Handset mode	**MODE** / **A** / **B** / **C** **BEEP** / **GOOD** / **ALL** / **ALL** **HAND SET LIGHT:** **PCAM STOPPED** / **OFF** / **OFF** / **OFF** **PCA AVAILABLE** / **ON** / **ON** / **ON** **PCA DELIVERING** / **FLASH** / **ON** / **FLASH** **PCA LOCK-OUT** / **OFF** / **ON** / **ON**
	5. Delayed call-back	**YES** - call-back alarm can be delayed from 10 mins up to 90 mins. **NO** - call-back will be cancelled for up to 2 mins or extended to 15 mins. To extend callback alarms, press and hold the stop key for 4 seconds . This allows the time to be extended.
	6. Display Sleep	**YES** - display goes blank after 2 minutes. **NO** - display stays on during operation.
	7. Chirp low alarms	**YES** - "chirp" alarm during use on battery/near end. **NO** - no "chirp" alarm.
	8. Continuous infusions	**YES** - Continuous infusions option in protocols. **NO** - Continuous infusions are not available.
	9. Loading doses	**YES** - Loading dose option appears in protocols. To activate this option "NEW PATIENT" is confirmed, The protocol also includes the loading dose. Start the PCA. **NO** - Loading dose are not available.
	10. Max. dose limits	**YES** - Dose limit option appears in protocols. **NO** - Dose limit are not available.
	11. Variable dose rates	**YES** - Variable dose rate option available. **NO** - Loading dose are not available.
	12. Comms identity number	Use arrows to set pump identity (between 000 and 127) for use with remote communications.
	13. Comms enabled	**YES** - RS232 Communications enabled. **NO** - RS232 Communications disabled.
	14. Nurse call	**YES** - Nurse call connector enabled. **NO** - Nurse call connector disabled.
	15. Continuous Print	**YES** - allows printing of events as they happen. **NO** - continuous printing disabled.
	16. Default Syringe	**YES** - default syringe enabled. **NO** - default syringe disabled.
	17. Syringe Type Locked	**YES** - syringe type locked to default syringe. **NO** - syringe type not locked to default syringe.
4	**TURN PCAM OFF**	When set-up is complete, turn key switch to **OFF** position to save selection.

PRE-SET PROTOCOL SET UP

Pre-set Drug names and safety limits apply to pre-set protocols during protocol selection and modification.

1	Turn key switch to **SET** position while pressing down **START** button.	
2	Enter access code **"2 5 1"**	
3	Select **PROTOCOL DEFAULT SET-UP**. Press **ENTER**.	
4	**MODIFY PROTOCOL**	Press to display current protocol summary. Use arrows to highlight a field, **ALTER** to enter that field and "+" and "-" arrows to select desired values. When field is correct press **CONFIRM** or **CANCEL**. Press **OK** to return to protocol summary.
5	Display will show the current protocol set-up in format:	

A PROTOCOL

Drug Name	**MORPHINE**	
Drug conc.	**1.0mg/ml**	
PCA dose	**1.0mg**	**(1.0 ml)**
Lockout period	**5 minutes**	
Occlusion level	**Level 0 to 10**	**(Default is 4)**
Continuous rate	**0ug/h**	**(0.0 ml/h)**
Loading dose	**0ug**	**(0.0 ml)**
Max. limit	**50mg**	**(50.0 ml)**
Limit duration	**4 hours**	
PCA delivery period	**STAT**	

6	**NEXT PROTOCOL**	Press to display the next protocol (pre-set protocols are identified as A to E).
7	**QUIT**	Press **QUIT** to return to main menu.
8	**TURN PCAM OFF**	When set-up is complete, turn key switch to **OFF** position to save selection.
9	**IMPORTANT:** The default protocols are a reference against which **PCAM** stores patient history and events. Changing the default set-up may reset all patient history stored in the unit as if **NEW PATIENT** had been selected. If Dose limits are not required for an individual protocol, select a dose limit of zero and **MAX OFF** will be displayed in the normal run screen. The volume values shown in the set-up screen will change automatically as the settings for the Concentration, PCA Dose etc. are changed. This provides an indication of the volume of the infusion that will be delivered to the patient.	

EXAMPLE ONLY

CLOCK SET

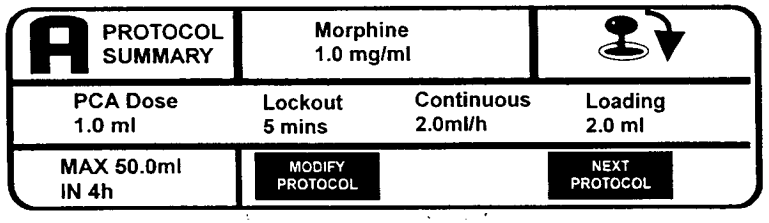
The internal clock is used to record patient history.

1	Turn key switch to **SET** position while pressing down **START** button.	
2	Enter access code **"2 5 1"**	
3	Select **CLOCK SET** from Menu. Press **ENTER**.	
4	Display will show current date and time programmed into unit. **NOV 08 1994 14:32** **(month : date : year : hours : mins)** **May clear patient information**	
5	**UP/DOWN ARROWS**	Use "+" and "-" arrows to change values in the highlighted field. When entry is correct press **NEXT**.
6	**NEXT**	Press to move the highlight from left to right and select the field to be changed.
7	**OK**	Press **OK** to save the date and time.
8	**TURN PCAM OFF**	When set-up is complete, turn key switch to **OFF** position to save selection.
9	**IMPORTANT:** The internal clock is the reference against which the **PCAM** unit stores patient history and events. Changing the clock will automatically reset the dates against which all new patient history is stored in the unit and may effect the presentation of the history graphs. Patient history should always be recorded and, if required, printed prior to changing the clock.	

USING PRE-SET PCAM PROTOCOLS

Operation of **PCAM** is greatly simplified by the use of PRE-SET PCA protocols. When the **PCAM** key switch is turned to the **SET** position the unit will automatically display pre-set **PROTOCOL A** if **NEW PATIENT** has been selected, or, display the previous protocol in use if **NEW PATIENT** has not been selected.

With the key switch in the **SET** position, it is possible for the user to modify the pre-set protocol using the **MODIFY PROTOCOL** button and select another pre-set protocol using the **NEXT PROTOCOL** button.



1	**TO MODIFY A PRE-SET PROTOCOL** **(NOTE: A modified protocol has no pre-set letter.)**	Press to **MODIFY PROTOCOL**. The protocol summary will be displayed. Use up/down arrows to highlight a field, **ALTER** to enter that field and "+" and "-" arrows to select desired values. When field is correct press **CONFIRM** or **CANCEL.** Display will show:-

A

PROTOCOL		
Drug Name	MORPHINE	
Drug conc.	1.0mg/ml	
PCA dose	1.0mg	(1.0ml)
Lockout period	5 minutes	
Occlusion level	4	
Continuous	0ug/h	(0.0 ml/h)
Loading dose	0ug	(0.0 ml)
Max. limit	50mg	(50.0 ml)
Limit duration	4 hours	
PCA delivery	STAT	

Press **OK** to return to protocol display.

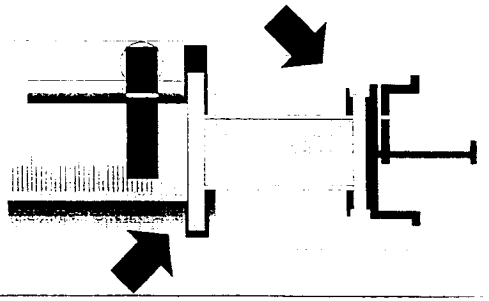
2	**TO CHANGE TO ANOTHER PRE-SET PROTOCOL**	Press **NEXT PROTOCOL** to display the step through the pre-set protocol. Pre-set protocols are identified as A to E. When the desired protocol has been selected it can used by turning the key switch to the **RUN** position, or, can be modified using the **MODIFY PROTOCOL**.
3	**TO CONFIRM PROTOCOL**	When ever a new protocol is selected, modified or the key switch is turned to the **SET** position, the **CONFIRM PROTOCOL** display will appear. Pressing **OK** automatically records the protocol and any changes in the **EVENT LOG** history.

DRAFT ONLY

OPERATING PROCEDURES

LOADING THE SYRINGE

1	Place the pump on a stable horizontal surface or secure to a suitable IV pole using the pole clamp supplied.
2	Prepare, load and prime the single use disposable syringe and PCA extension line using standard aseptic technique. **IVAC** recommend the use of a PCA set with an anti-syphon valve at the syringe and a non-return valve at the Y-site (if fitted). If an anti-syphon valve with a high "cracking" pressure is used, it may cause false occlusion alarms and it may be necessary to adjust the pumping pressure alarm level. See General Options.
3	Open the cover using the **PCAM** key in the lock next to the handle.
4	Squeeze the finger grips on the plunger holder and slide the mechanism all the way to the left.
5	Lift the syringe clamp and rotate to the left.
6	Insert the syringe plunger into the slot on the plunger holder. Squeeze the finger grips on the plunger holder and slide to the right until the syringe finger flanges locate into the V slot. **ADVANCE THE SYRINGE UNTIL THE FINGER FLANGES TOUCH THE FRONT FACE OF THE V-SLOT CLOSEST TO THE SYRINGE CLAMP (THIS IS IMPORTANT TO PREVENT DELAYED START UP OF INFUSION).**
7	Rotate the syringe clamp forwards until it locks onto the syringe barrel.
8	Check that the syringe plunger, finger flanges and PCA set are correctly located in their slots. Close the cover until it locks securely.



IMPORTANT NOTES
ONLY USE A SYRINGE OF THE TYPE AND SIZE INDICATED IN THIS MANUAL AND SHOWN IN THE PUMP DISPLAY. USING AN INCORRECT SYRINGE COULD ADVERSELY EFFECT THE ACCURACY OF THE INFUSION AND THE PERFORMANCE OF PUMP.
WHEN INITIALLY FILLING THE SYRINGE, ALLOW FOR THE VOLUME OF FLUID CONTAINED IN THE EXTENSION LINE AND RETAINED IN THE SYRINGE AT THE END OF INFUSION AS THIS "DEADSPACE" WILL NOT BE INFUSED.

OPERATING PROCEDURES (continued)

STARTING PCAM		
1	**AC POWER**	Connect unit to AC power supply using the AC power cable.
2	**SET**	Insert **PCAM** key in front panel switch. Turn to **SET** position. The unit will automatically operate from its own internal rechargeable battery if it is switched **ON** without the AC power connected.
3	**NEW PATIENT?**	Answering **NO** will retain all previous patient history. **YES** will automatically reset the patient history to zero. Check time and date is correct and answer **YES** or **NO**.
4	**SELECT/ MODIFY PROTOCOL**	Carefully check the protocol displayed. If required, press **MODIFY PROTOCOL** to adjust the current protocol, or, **NEXT PROTOCOL** to select an alternative pre-set protocol.
5	**RUN**	Turn the **PCAM** key to the **RUN** position and remove from unit.
6	**CHECK PROTOCOL**	Carefully check that protocol is correct. Press **OK**.
7	**CONFIRM SYRINGE**	Check that the syringe type and size being used matches display. If required, the make of syringe can be changed by pressing the **CHANGE TYPE** button. Press **OK**.
8	**PURGE (if required)**	The **PURGE** buttons can only be used when the cover is open and the key switch is in the **RUN** position. Press the **PURGE** buttons together until fluid flows and priming of the syringe extension line is complete. The audible alarm will operate during use of the **PURGE** buttons and the volume used during priming will be shown in the volume infused display.
9	**CONNECT PATIENT**	Connect the PCA extension line to the patient access device. Recheck the protocol.
10	**START**	Press **START** to commence **PCAM** operation. **PCA AVAILABLE** will be displayed with the protocol summary, demand and drug totals. If selected, a loading dose will be delivered. The **AMBER STOP** light will be replaced by the **GREEN START** light to indicate that the pump is operating and PCA is available.
11	**STOP**	Press **STOP** to halt operation and/or silence any alarms which may occur. The **AMBER** light will replace the **GREEN** light. **PCAM** will continue operation until the syringe is almost empty, **STOP** is pressed or an alarm condition which automatically stops the pump is encountered.

IMPORTANT NOTES
EACH TIME THE UNIT IS SWITCHED ON, CHECK THAT THE ALARM BEEPS TWICE AND THAT ALL THE SEGMENTS OF THE DISPLAY AND THE GREEN AND AMBER LIGHTS ARE ILLUMINATED DURING THE SELF TEST ROUTINE.
THE KEY SWITCH SHOULD NOT BE TURNED FROM OFF TO SET POSITION WHILE THE SYRINGE EXTENSION LINE IS CONNECTED TO THE PATIENT
NO ALARMS ARE DISABLED DURING A BOLUS INFUSION, OR USE OF THE PURGE BUTTON.

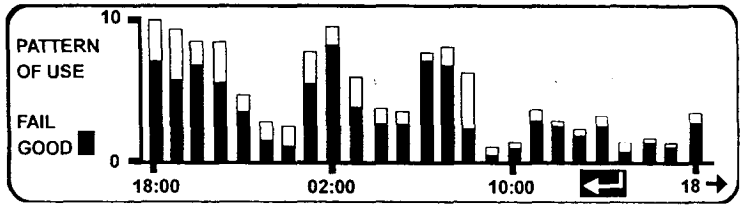
PCAM PATIENT HISTORY

Each time the **PCAM** unit is switched **ON** it will ask if this is a new patient. Pressing **YES** will provide opportunity to re-set patient history and produce a print of the previous patients history. Pressing **NO** continues with the current protocol and retains all protocol records, event history, graphs etc.

The **PCAM** will retain up to 1500 individual events in a rolling memory. Following selection of a new patient, it remains possible in technician mode to access previous patient(s) history still held in memory.

Patient history can be accessed at any time by pressing the **HISTORY** button. **PCAM** provides a clear rolling 24 hour graphical representations of the PCA demand pattern and the drug administered to the patient. The graphs are updated when the history button is pressed and give values for each completed hour and the current hour.

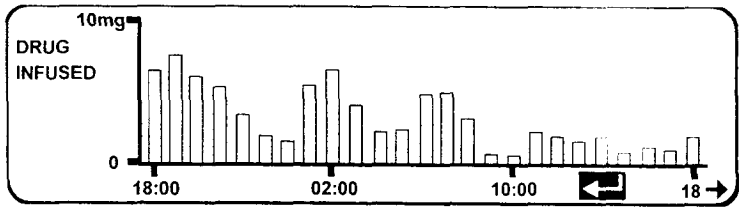
PCA PATTERN OF USE



Record of the last 24 hours good and failed PCA demands. The good demands are indicated by the shaded section of the graph and the failed demands by the clear section. The latest hour is shown at the right side of the display.

This graph provides a clear picture of good and bad PCA demands and pattern of the patients usage. Used in conjunction with the **DRUG INFUSED** graph, this display helps to indicate if the PCA protocol needs modification and when to end treatment.

DRUG INFUSED

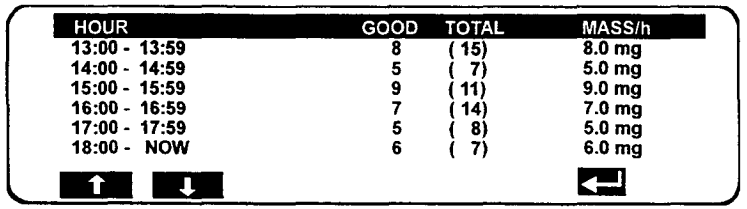


Record of the total amount of drug administered to the patient over the last 24 hours. The latest hour is shown at the right side of the display. This graph provides a clear picture of the actual drug administered, including loading dose, continuous background infusions, clinician over-rides and protocol changes.

Used in conjunction with the **PATTERN OF USE** graph, this display helps to indicate relative pattern of the demand pattern and the actual drug administered.

PCAM PATIENT HISTORY (continued)

24 HOUR REVIEW

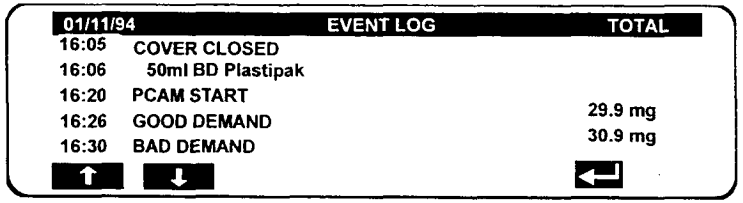


HOUR	GOOD	TOTAL	MASS/h
13:00 - 13:59	8	(15)	8.0 mg
14:00 - 14:59	5	(7)	5.0 mg
15:00 - 15:59	9	(11)	9.0 mg
16:00 - 16:59	7	(14)	7.0 mg
17:00 - 17:59	5	(8)	5.0 mg
18:00 - NOW	6	(7)	6.0 mg

Hour by hour record of the last 24 hours good and total PCA demands and the total dose per hour.

This information provides the accurate demand pattern and drug infused values from which the other graphs are derived.

PCAM EVENT LOG



01/11/94	EVENT LOG	TOTAL
16:05	COVER CLOSED	
16:06	50ml BD Plastipak	
16:20	PCAM START	
16:26	GOOD DEMAND	29.9 mg
16:30	BAD DEMAND	30.9 mg

Record of events since "**NEW PATIENT**" selected. Including, protocol selection and changes, patient demands etc. The event log will also record all alarms.

All events are recorded against date, clock and total drug infused.

CLINICIAN OVER-RIDE

The clinician over-ride feature can be used in **RUN** mode to administer an additional bolus dose or continuous background infusion of a limited dose and duration, for example during the PCA lock-out period. The clinician over-ride is a special feature which can be configured according to the specific clinical situation.

Clinician over-ride can also be used in **SET** mode to allow modification of the pre-set PCA Protocol when this option has been disabled for normal use.

CLINICIAN OVER-RIDE - BOLUS/CONTINUOUS INFUSION

1	With key switch to **RUN** position and **START** green light illuminated.		
2	Press and hold down **CLINICIAN OVER-RIDE** button for 2 seconds.		
3	Use **"+"** and **"-"** arrows and **NEXT** to enter three figure pre-programmed clinician access code **"n n n"**. See **TECHNICIAN ACCESS CODES**.		
4	**Bolus or continuous**	**Bolus**	Additional bolus dose delivered, for example during lock out period. Additional PCA doses cannot be delivered at same time. Normal PCA lock-out period operates after clinician over-ride bolus has been delivered.
		Continuous	Dose is delivered as a background continuous infusion. Additional Patient or Clinician over-ride PCA doses can be delivered while continuous over-ride dose is being delivered.
5	**Clinician dose**	Use **+** and **-** arrows to select dose to be delivered. Press **OK** when correct value entered.	
6	**Delivery time**	Use **+** and **-** arrows to select period over which the dose is to be delivered. Press **OK** when correct time entered.	
7	**BEGIN BOLUS**	**YES** - Clinician bolus/continuous will be delivered to patient. **NO** - Quit set up and return to normal operation.	
8	**IMPORTANT**: The delivery of the clinician over-ride continuous infusion will automatically halt while a Patient or Clinician over-ride bolus is being administered. To cancel clinical over-ride during delivery, switch the key switch to the **SET** position and back to **RUN**, clinical over-ride will cancel when protocol is confirmed.		

CLINICIAN OVER-RIDE - MODIFY PRE SET PROTOCOL

1	With key switch to **SET** position. Press and hold down **CLINICIAN OVER-RIDE** button for 2 seconds.
2	Use **"+"** and **"-"** arrows and **NEXT** to enter three figure pre-programmed clinician access code **"n n n"**. See **TECHNICIAN ACCESS CODES**.
3	Protocol summary will be displayed with **MODIFY PROTOCOL** button. Modify protocol as normal.

ALARM PROCEDURES

Alarms are indicated by a combination of an audible alarm, flashing amber **STOP** light and a descriptive message in the display. The alarm volume can be adjusted by rotating the slot in the alarm outlet found on the base of the unit.

A continuous audible alarm indicates that the infusion has stopped. First press **MUTE** to silence the alarm for a maximum of 2 minutes, then check the display for an alarm message. Press **STOP** to cancel the alarm message. When the cause for the alarm has been rectified press **START** to restart operation.

DISPLAY	DESCRIPTION
"COVER OPENED"	**COVER OPENED DURING OPERATION** The cover has been opened, or cover lock operated, during operation. Check cover and lock.
"DRIVE DISENGAGED"	**PUMP DRIVE DISENGAGED** The drive system has been disengaged during operation. Unlock and open the cover. Check the finger grips and the position of the syringe.
"LINE OCCLUSION"	**EXCESSIVE PUMPING PRESSURE** Pumping pressure has reached the alarm limit. Unlock and open the cover, squeeze finger grips on the plunger holder to release the drive mechanism and relieve any excessive pressure in the syringe and patient line. Identify and remove the cause of the blockage in the drive, syringe, or administration system before restarting the infusion.
"SYRINGE ERROR"	**SYRINGE SIZE ERROR / FITTED INCORRECTLY** Incorrect size of syringe has been fitted, the syringe clamp has not been positioned correctly on the syringe or has been disturbed during operation or plunger is not fitted in plunger slot. Unlock and open the cover, check syringe size, position of syringe clamp, syringe and plunger.
"CHECK HANDSET"	**PATIENT HAND SET FAILURE** Patient hand set has become faulty or disconnected during operation. Check operation and connection of the hand set to the unit. Press **START** to continue if operation without the hand set is required.
"BATTERY LOW"	**BATTERY CHARGE LOW WARNING** Battery charge low with 30 minutes operation remaining. Battery indicator will flash and after 30 minutes a continuous audible alarm will indicate that the battery is exhausted. Reconnect to AC power supply to continue operation and charge internal battery.

ALARM PROCEDURES (continued)

DISPLAY	DESCRIPTION
"BATTERY EXHAUSTED"	**BATTERY EXHAUSTED** Internal battery exhausted. To silence the alarm switch the key switch to the **OFF** position and reconnect unit to AC power supply. Restart operation on AC power while charging the internal battery switch to the **RUN** position.
"NEAR END OF SYRINGE"	**NEAR END OF SYRINGE WARNING** Syringe almost empty with about 6% of its volume remaining. Press **START** to silence alarm and continue operation. Display will flash **SYRINGE NEAR EMPTY.**
"SYRINGE EMPTY"	**SYRINGE EMPTY - END OF INFUSION** The pump has reached the end of the infusion. About 1% of the syringe volume will remain in the syringe helping to prevent the infusion of air bubbles into the PCA set.
"AC POWER FAIL"	**AC POWER SUPPLY DISCONNECTED WARNING** AC Power has been disconnected and the pump is operating on battery power. Reconnect AC power supply or press **START** to silence the alarm and continue battery operation. The display will flash **ON BATTERY**. The alarm will automatically cancel if the AC power supply is reconnected.
"3" BEEPS	**NURSE ATTENTION WARNING** Unit left switched **ON** for over 2 minutes without starting operation. Press **STOP** or any of the control buttons to silence the alarm for a further 2 minutes. Alternatively, press and hold down **STOP** for 2 seconds to silence the alarm for 15 minutes, or press for 4 seconds to enter delayed call-back mode - see **GENERAL OPTIONS**.
"MAX. DOSE EXCEEDED"	**MAXIMUM DOSE LIMIT REACHED** The total dose limit has been reached. Refer to clinician. If restart is required, it is necessary to turn key switch to **SET** then back to **RUN**.
"MALFUNCTION"	**INTERNAL MALFUNCTION** The alarm system has detected an internal malfunction. Note the malfunction code. Remove unit from service for examination by a qualified service engineer.

PRINTING

A printer fitted with a serial interface (or cable with parallel to serial converter) can be connected to the **PCAM** unit, either during normal PCA operation, or, following use. Printing patient history provides a permanent record of the patients history and can be used for analysis away from the bedside.

All patient history, including protocols and the 24 hour demand pattern and drug dose administered graphs are available for printing.

When connected to the printer, the **PCAM** can also be configured to provide line by line continuous printing of all events, patient demands etc. as they occur at the bedside. See General Options.

PRINTING OPTION	PROCEDURE
CONTINUOUS MODE	• Enable Continuous printing by selecting **YES** in General Options. • Connect printer. • All events will be printed as they occur.
PROTOCOL SUMMARY	• Connect printer • Turn key to **SET** position. • Press **PRINT** button. • All protocol information will be printed with patient header.
PATIENT HISTORY	• Connect printer. • Press **PRINT** button. • All protocol information, demand and drug totals, 24 hour graphs and records will be printed with patient header.
EVENT LOG	• Connect printer. • Press **HISTORY** button until event log is displayed. • Use arrow buttons to position display at start point for events to be printed. • Press **PRINT** button. • All events will be printed from information on screen forward with time, date and patient header.
EVENT LOG AT NEW PATIENT	• Connect printer. • Press **PRINT** button. • All events will be printed from the patient event log.

BATTERY OPERATION AND FUSE REPLACEMENT

BATTERY OPERATION AND CHARGING

This **IVAC syringe pump** is fitted with an internal rechargeable battery allowing continued operation when the AC power is unavailable, for example during patient transfer or AC power failure.

A fully charged battery will provide over 6 hours operation independent of the infusion rate. From the battery low alarm it will take about 24 hours to fully recharge when reconnected to the AC power supply, whether the unit is in use or not.

The battery is automatically charged during AC operation and whenever the unit is connected to the AC power supply and the AC power indicator is illuminated.

It is good practice to periodically operate the unit on battery power until the battery low alarm then charge the battery to confirm battery operation and charging. When not in use, connect the unit to the AC power supply in order to maintain the battery in the fully charged state.

The battery is a maintenance free, sealed lead acid type and requires no routine servicing. However, to achieve optimum operation, ensure that the battery is fully recharged after full discharge, before storage and at regular 3 month intervals during storage.

REPLACING THE INTERNAL FUSE

If the pump continually illuminates the battery symbol and the AC power indicator light does not illuminate when the pump is connected to the AC power supply and switched **ON**, suspect that either, the power supply fuse in the AC power plug, or, the internal fuse has blown.

First check the power supply fuse in the AC plug, if the AC power indicator light does not illuminate proceed to check the internal fuse. To inspect and replace the internal fuse, first switch the power **ON/OFF** switch to the **OFF** position and disconnect the unit from the AC power supply.

Carefully support the unit upside down and remove the six fixing screws. The pole clamp and base plate may be left in position.

Carefully separate the upper and lower sections of the unit and identify fuse holder reference FS1 on the power supply pcb in the lower case assembly.

Unscrew fuse holder cap, remove and check fuse. If the fuse has blown, fit a new fuse of the correct type and rating. Do not exceed the current rating specified.

VOLTAGE	FUSE TYPE	FUSE SIZE
220/240V	**T63mA Time Lag**	**(5mm x 20mm)**
110/120V	**T125mA Time Lag**	**(5mm x 20mm)**

If the internal fuse fails again after a short period, or the fuse in the power supply plug fails, take the unit out of service for examination by a qualified service engineer.

MAINTENANCE, CLEANING AND STORAGE

ROUTINE MAINTENANCE PROCEDURES

To ensure that this instrument remains in good operating condition, it is important to keep it clean and carry out the routine maintenance procedures described below. All servicing should only be performed by a qualified service engineer with reference to the **IVAC** Technical service manual for this product (Service Manual reference: **5000PB00004**).

If the unit is dropped, damaged, subjected to excessive moisture or high temperature, immediately take it out of service for examination by a qualified service engineer.

INTERVAL	ROUTINE MAINTENANCE PROCEDURE
As required	Thoroughly clean external surfaces of the unit before and after use and after a prolonged period of storage.
12 Monthly	1. Inspect AC Power Supply plug and cable for damage. 2. Perform functional **OPERATION AND ALARM TEST**. 3. Perform instrument **SELF TEST ROUTINE**. 4. Perform electrical safety checks. 5. Perform rate accuracy verification test. 6. Perform pressure calibration verification test. 7. Operate the unit on battery power until the battery low alarm then charge the battery to confirm battery operation and charging.

CLEANING AND STORAGE

Before cleaning always ensure that the key switch is in the **OFF** position and disconnect the unit from the **AC** power supply. Do not steam autoclave, ethylene oxide sterilise or immerse this instrument in any fluid.

Periodically clean the pump by wiping over with a lint free cloth lightly dampened with warm water and a standard disinfectant/detergent solution. Avoid excess fluid and never allow liquid to enter the case.

Do not use aggressive solvents or abrasive cleaning agents as these may damage the exterior surface of the unit.

The syringe and extension line are disposable single use items and should be discarded after use according to their manufacturers instructions.

If the pump is to be stored for an extended period it should be first cleaned and the internal battery fully charged. Store in a clean, dry atmosphere at room temperature and, if it is available, employ the original packing for protection.

Once every 3 months during storage, carry out the functional tests described in **OPERATION AND ALARM TEST** and **SELF TEST ROUTINE** and ensure that the internal battery is fully charged.

DISPOSAL

The pump should be disposed of in an environmental manner. To ensure no risk or hazard remove the internal rechargeable battery and the nicad battery (component B1) from the control board and dispose of as outlined by the local country regulations. Do not send back to manufacturer. All other components can be safely disposed of in the normal manner.

APPENDIX A - SELF TEST ROUTINE

The self test routine is designed to allow confirmation of many of the units functions, defaults and calibrations without requiring internal inspection. It does not represent a full calibration check. To enter self test routine:-

	TO ENTER SELF TEST ROUTINE
1	Turn key switch from **OFF** to **SET** position while holding down the **START** button.
2	Hold down **START** button and press power **ON/OFF** switch to **ON** position.
3	Enter "**1 2 3**" using the "**+**" , "**-**" and **NEXT** buttons.
4	Press **ENTER** to commence self test sequence.
5	The unit will now proceed through a series of tests as described below. Press the **NEXT** button to move to the next test, or press the **QUIT** button to exit the self test mode and return to normal operation.
6	**SHOULD THE UNIT FAIL THIS TEST SEQUENCE, IT SHOULD BE TAKEN OUT OF USE AND INSPECTED BY A QUALIFIED SERVICE ENGINEER.**

	DISPLAY	TEST DESCRIPTION
1	SOFTWARE REVIEW	**SOFTWARE/SET UP REVIEW:** Including software version, program crc, language, communications fitted.
2	SYRINGE REVIEW	**REVIEW SET UP OF SYRINGE CALIBRATION DATA:** Including syringe calibration, occlusion calibration and syringe range.
3	_._ _ V	**INTERNAL PSU VOLTAGE:**
4	"BEEP"	**AUDIBLE ALARM TEST:** Check alarm sound continuously.
5		**DISPLAY AND BACKLIGHT DIM TEST:** Check that all the display is operating and that the display operates on full backlight for the first part of the test, dims for the second part and then switches off at the end of the test.
6	Press S1	**TOUCH PANEL SWITCH TEST:** Press buttons in turn from S1 to S10 from **START** to **PURGE** until reach end of test
7	FLASHING "LED's"	**INDICATOR LED TEST:** Check that the **STOP** and **START** LED's are flashing.
8	DECLUTCH	**DECLUTCH SWITCH TEST**: Squeeze plunger holder finger grips and check that the display alternates between 1 (engaged) and 0 (disengaged - finger grips squeezed together).

APPENDIX A - SELF TEST ROUTINE (continued)

	DISPLAY	TEST DESCRIPTION
9	EOI opto: 0	**NEAR END OF INFUSION TEST**: Starting with an empty, extended 50/60ml syringe on the unit, squeeze the finger grips and move the plunger holder slowly to the left. Check that the display switches from 0 to 1. The position at which the display changes will depend on the syringe type being used. (For example 6ml on a B-D Plastipak 50/60ml syringe and 3ml on a TERUMO 50ml syringe - see service manual for values).
10	Grid opto: 0	**LINEAR GRID TEST**: Squeeze the finger levers and position the drive mechanism to the right, then slowly move the syringe plunger holder to the left observing the display alternate between **0** (OPTO over slot) and **1** (OPTO over bar).
11	Plunger opto: 1	**PLUNGER DETECTOR TEST:** Press plunger plate button. Check display switches from **1** (No syringe fitted) to **0** (Syringe plunger fitted).
12	Motor/encoder: 1	**MOTOR ENCODER TEST**: Motor is pulsed while encoders are tested. Check display changes from **0** to **1** as encoders pass.
13	Cover detect: 0	**COVER DETECT TEST:** Open and close the cover. Check that display changes from **0** (cover open) to **1** (cover closed).
14	Syringe pot: _ _ _	**SYRINGE SIZE DETECTION SYSTEM:** Lift syringe clamp and check that the number shown in the display increases within the normal range (approx. **045 to 215**).
15	Beam value: _ _ _	**PUMPING PRESSURE DETECTION TEST**: Remove syringe and confirm that value is within normal range **(-020 to +020)**. Gently press back on the plunger holder and observe the value increase.
16	Handset: OFF	**PATIENT HAND SET TEST:** Connect patient hand set. Check display switches from **OFF** to **ON** as the button is pressed.
17	Key switch: SET	**KEY SWITCH TEST:** Turn key from **SET** position to **RUN** position. Check display changes.
18	Nursecall on/off/on ...	
19	CONFIGURATION SUMMARY	Summary of user defined options selected.
20	NEXT	Returns unit to normal operation.

APPENDIX B - TECHNICIAN ACCESS CODES

The following list is provided for reference purposes only. Technical access codes should not be used without reference to the PCAM Technical Service Manual (reference: 5000PB00004).

CODE	TITLE	DESCRIPTION
123	SELF TEST	Self test routine steps through pump calibration, configuration and set-up. No values can be changed in this mode.
125	SELF TEST	Self test routine as above, but starting at Display test.
243	SYRINGE CALIBRATION	Use to calibrate the syringe size detection system. Calibration test gear required.
251	GENERAL CONFIGURATION	Use to select user defined options including:- **- Drug names and safety limits** **- General options** **- Protocol default set-up** **- Clock set**
359	SYRINGE RANGE	Use to select syringe types when special hardware if fitted. For example: Universal, Janpol or B.Braun Perfuser.
	LANGUAGE	Use to set screen language. For example: English, French or German.
376	SERVICE LOG REVIEW	Use to review the last 10 error codes that have been generated by the safety checking systems. Linked back to the date on which the error occurred. Also displays the number of hours that the pump has been used since last reset.
501 502	MASS AND VOLUME DOSING	The standard default is mass dosing. Volume dosing allows all safety limits, protocol dose values and PCA doses to be programmed ml. **Note: when a new pump mode is selected all preset drug and protocol data will be reset to default values.** Code 501 - enables Mass Dosing Code 502 - enables Volume dosing
717	OCCLUSION CALIBRATION	Use to calibrate the pumping pressure detection system. Calibration test gear required.
794	ACCESS FULL EVENT LOG	Having entered the code, switch the PCA off and on again. To view the event log, you will be able to scroll back past "NEW PATIENT" through all the event currently stored. DO NOT clear previous patient information.
835	CLINICIAN OVER-RIDE ACCESS CODE	Use to enter the three figure number which allows access to the clinician over-ride functions
999	LOAD DEMONSTRATION HISTORY	Use to load 24 hours of "dummy" patient history. Automatically reset when NEW PATIENT selected.

APPENDIX C - SPARE PARTS LIST

A comprehensive list of spare parts for **IVAC** syringe pumps is included within the service manual. This can be ordered from **IVAC**, or our authorised distributor. For part number please refer to summary spare parts list below.

PART NUMBER	DESCRIPTION
5001FAOPT71	**PCAM** Directions for Use. Model P5000. English.
5000PB00004	**PCAM** Service Manual. Model P5000. English.
5000SP00008	Printer Cable 9 to 25 pin (9-pin female (PCAM) to 25-pin male (printer)).
5000SP00010	Citizen PN60 Printer Cable (9-pin female (PCAM) to 26 pin AMP 17823404).
1000SP01008	Comms Cable (9-pin female to 9-pin female).
0000EL00004	Internal Battery - 6v NP2.6-6 Rechargeable.
0000EL00287	Fuse - T63mA (Time Lag 5x20mm) - 220/240V units.
0000EL00280	Fuse - T125mA (Time Lag 5x20mm) - 110/120V units.
1001FAOPT91	AC Power Cable - U.K.
1001FAOPT92	AC Power Cable - European
1001FAOPT93	AC Power Cable - Unterminated.
0000ME00026	Foot - Self Adhesive.
1000SP01015	Pole Clamp Assembly.
5000LB00020	Label Set P5000.
5000LB00002	Label - Front Panel - P5000 - English.

TEST, CALIBRATION AND SERVICE EQUIPMENT

These **IVAC** syringe pumps have been designed to allow simple and low cost servicing. Standard components are employed wherever possible and no special test or calibration tools are required. However, the following items may be useful for general servicing.

PART NUMBER	DESCRIPTION
0000TG00020	Occlusion Test Gear.
0000TG00002	Linear Accuracy Test Gear.
0000TG00032	**PCAM** Cover Detect Actuator Magnet.
0000TG00055	Syringe Sizing Spacer.
5000JG00001	Cradle P5000.
0000JG00014	Plunger Detect Protector.
1000EL00043	Ribbon Cable Extension.

APPENDIX D - OCCLUSION PRESSURE LIMITS

OCCLUSION PRESSURE LIMITS FOR COMPATIBLE SYRINGES

IVAC 50ML SYRINGE - VARIOUS ALARM LEVELS

The following tables show the worst case values for line pressure, time to alarm and bolus volume that can be expected in the event of an occlusion when the IVAC 50ml syringe is selected.

ALARM LEVEL	RATE (ml/h)	MAXIMUM TIME TO OCCLUSION ALARM (min:sec)	NOMINAL OCCLUSION PRESSURE (mmHg)	MAXIMUM INFUSION PRESSURE (mmHg)	MAXIMUM BOLUS VOLUME (ml)
0	1.0	2:00	0	50	0.1
1	1.0	8:00	92	110	0.2
2	1.0	20:00	184	220	0.3
3	1.0	33:00	276	330	0.5
4	1.0	52:00	368	450	0.7
5	1.0	65:00	460	560	0.9
6	1.0	85:00	552	670	1.0
7	1.0	102:00	644	780	1.2
8	1.0	120:00	736	890	1.6
9	1.0	140:00	828	1000	1.8
10	1.0	155:00	920	1100	2.0

ALARM LEVEL	RATE (ml/h)	MAXIMUM TIME TO OCCLUSION ALARM (min:sec)	NOMINAL OCCLUSION PRESSURE (mmHg)	MAXIMUM INFUSION PRESSURE (mmHg)	MAXIMUM BOLUS VOLUME (ml)
0	5.0	01:00	0	50	0.1
1	5.0	02:00	92	110	0.2
2	5.0	05:00	184	220	0.3
3	5.0	07:00	276	330	0.5
4	5.0	10:00	368	450	0.7
5	5.0	12:00	460	560	0.9
6	5.0	15:00	552	670	1.0
7	5.0	17:00	644	780	1.2
8	5.0	20.00	736	890	1.6
9	5.0	24.00	828	1000	1.8
10	5.0	26.00	920	1100	2.0

APPENDIX E - TRUMPET AND START-UP CURVES

In this instrument, as with all infusion systems, the action of the pumping mechanism and variations in individual syringes cause short-term fluctuations in rate accuracy.

The following curves show typical performance of the system in two ways: 1.) The accuracy during various time periods over which fluid delivery is measured (trumpet curves), and 2.) the delay in onset of fluid flow when infusion commences (start-up curves).

TRUMPET CURVES

Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or 'observation windows', not continuous data versus operating time. Over long observation windows, short term fluctuations have little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short term fluctuations have greater effects as represented by the "mouth" of the trumpet.

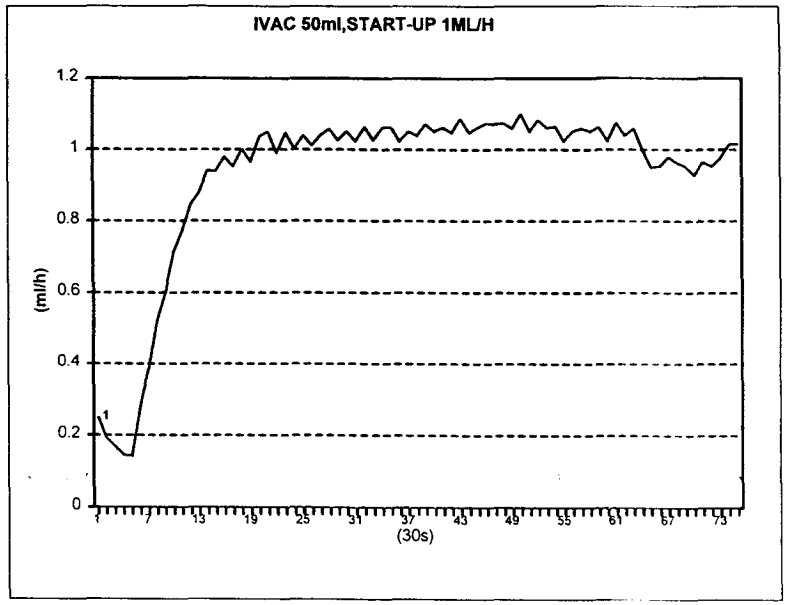
Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Because of the clinical impact of short term fluctuations on rate accuracy depends on the half-life of the drug being infused and the degree of inter vascular integration, the clinical effect cannot be determined from the trumpet curves alone.

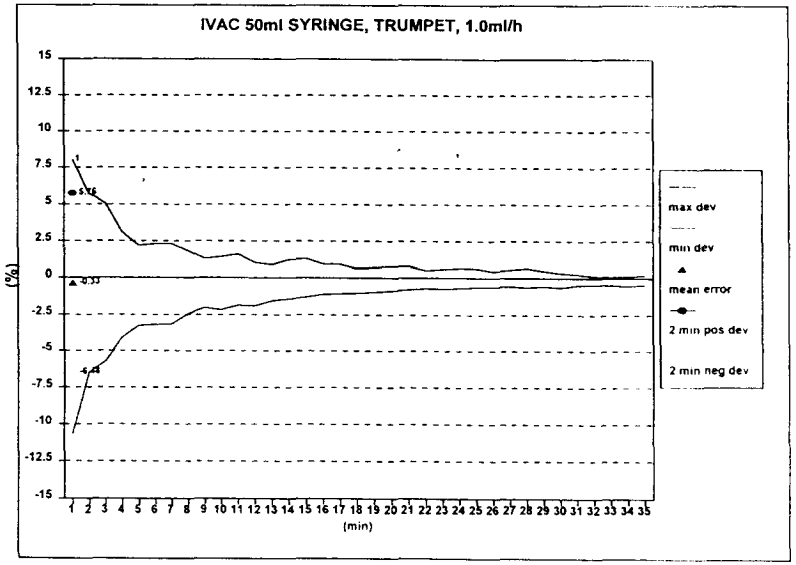
START-UP CURVES

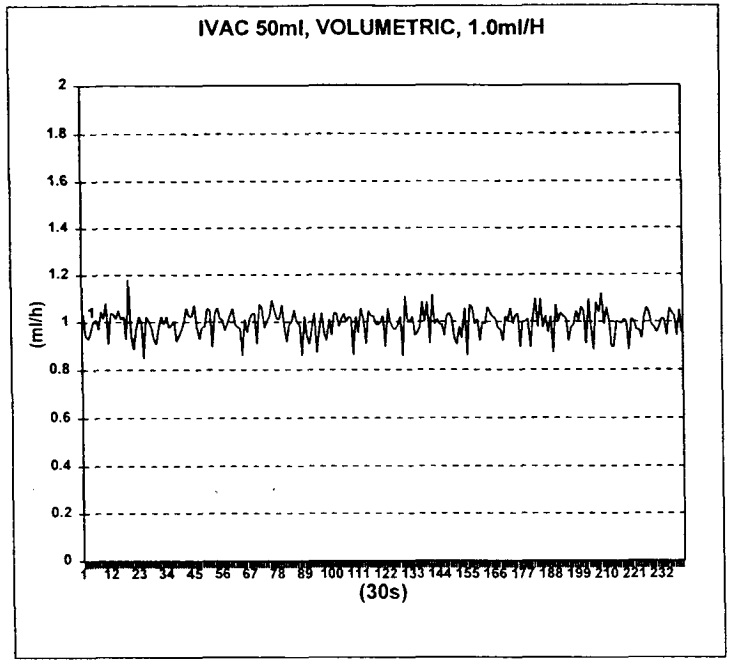
The start-up curves represent continuous flow versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data.

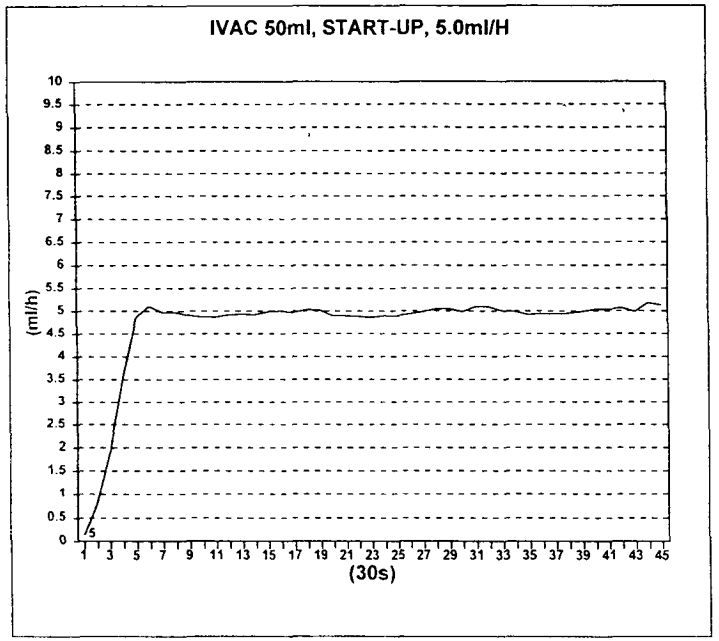
Long term accuracy of the IVAC 'P' Series syringe pumps in combination with the IVAC 50ml syringe is considered within +/-2% typical for rates of 1.0ml/hr and above.

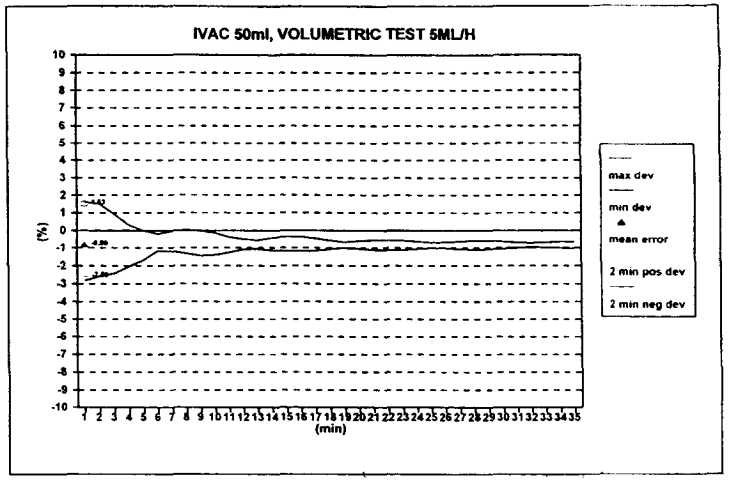
WARNINGS
Start-up and trumpet curves may not be indicative of operation under negative pressure.
Differences in factors such as size and plunger force in compatible syringes produced by other manufacturers can cause variations in accuracy and trumpet curves as compared to those represented. Additional curves for compatible syringes are available upon written request.
For applications where flow uniformity is a concern, rates of 1.0ml/hr or above are recommended.

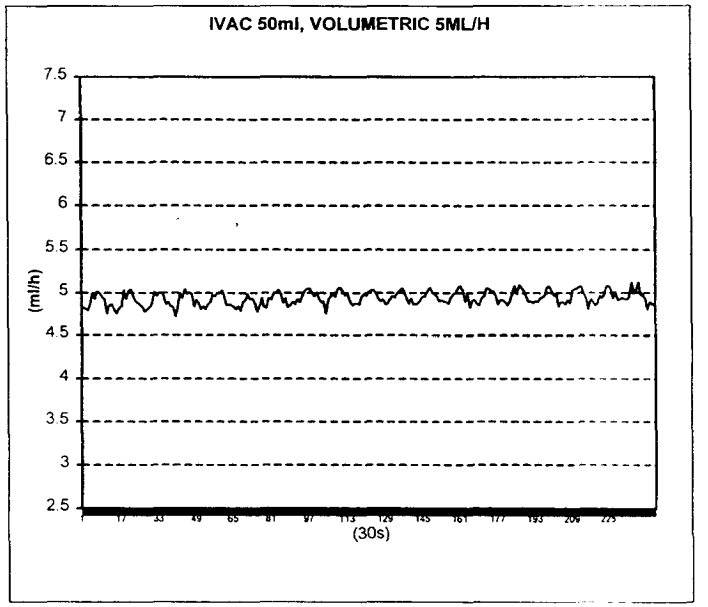


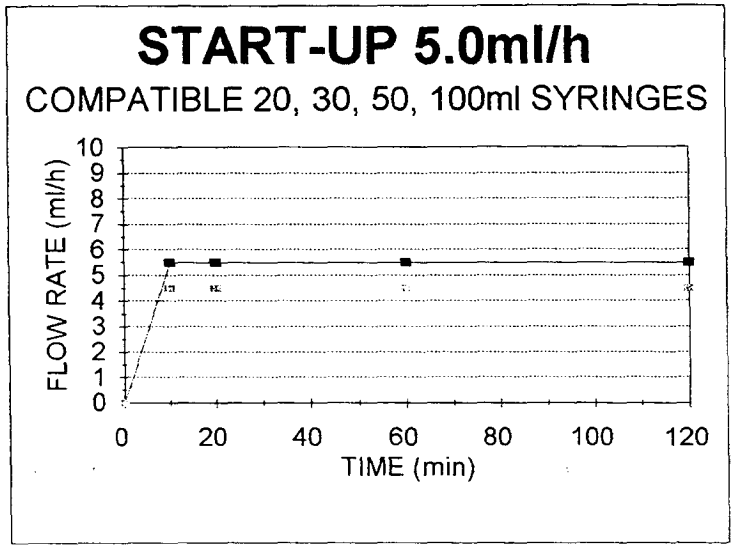


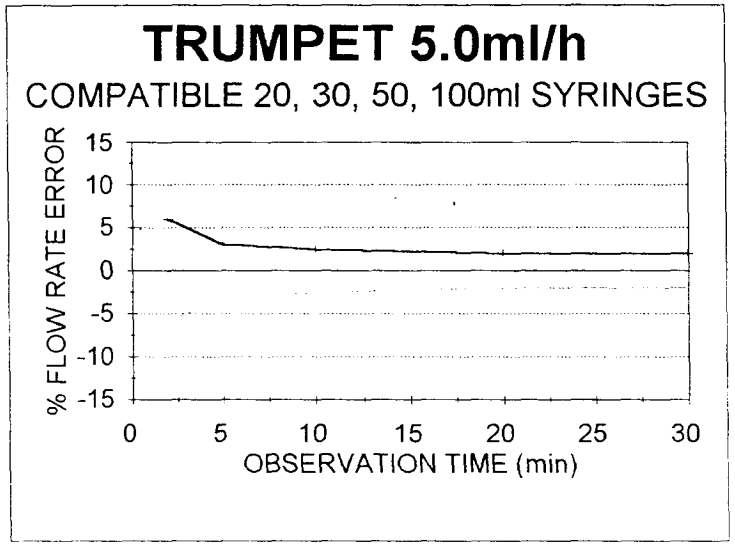

IVAC 50ml, VOLUMETRIC, 1.0ml/H
(ml/h)
(30s)


IVAC 50ml, START-UP, 5.0ml/H
(ml/h)
(30s)


IVAC 50ml, VOLUMETRIC TEST 5ML/H
(%)
(min)
max dev
min dev
mean error
2 min pos dev
2 min neg dev


IVAC 50ml, VOLUMETRIC 5ML/H
(ml/h)
(30s)





Err Max: +6.0%
Err Min: -6.0%

Note: Combined Startup and Trumpet Data above excludes Terumo 20ml and 30ml syringes.

APPENDIX F - TECHNICAL DESCRIPTION

The following details outline the safety checks designed into the IVAC 'PCAM' syringe pumps to minimise the possibility of under/over infusions.

1. MONITORING OF THE SYSTEM CLOCK FREQUENCY

The system clock , which is used to control the rate of the pump is derived from the microprocessor crystal oscillator.

A watchdog circuit is implemented in the pump to monitor the correct time period. The watchdog circuit requires the microprocessor to send a reset pulse every 10mS to stop the counter from timing out and triggering the watchdog alarm. The reset signal has to be in a time ' window' of between 8 to 12mS. If it is either too fast or too slow the watchdog hardware will detect this and generate a alarm.

Additionally, on power up the watchdog is allowed to time-out and the period is measured and tested to be within a set tolerance. This then confirms that both the microprocessor crystal and the watchdog crystal frequencies are correct.

2. DETECTION OF LINEAR MOVEMENT

A linear grid is incorporated in the unit to detect the movement of the pumping mechanism. This movement is monitored using a opto switch which passes over the 'bars' and 'slots' of an etched grid. If it is detected that the mechanism is either moving too fast or too slow then an error code will be displayed, the motor drive will be disabled and the pump will stop.

3. CONTROL OF LINEAR SPEED

The pump mechanism is driven using a d.c. motor which provides feedback for the control system from two opto switches. To enable the motor drive there are three transistors which need to be turned on. The correct operation of these transistors is tested on power up.

The control system monitors the feedback from the opto encoders and adjusts the motor on time to maintain the required speed. If there are no encoder signals feedback, indicating that an opto has failed or the transmission has jammed, an error code will be displayed and the pump will fail-safe

If there are too many encoders detected by the encoder feedback indication that a transistor has gone short circuit an error code will be displayed and the pump will fail-safe.

4. WATCHDOG CIRCUIT

The watchdog circuit monitors the correct operation of the microprocessor. In the event of a failure detected the watchdog will enable a alarm and disable the motor drive.

5. UNITS OF MEASUREMENT USED IN THE CALIBRATION OF THE OCCLUSION DETECTION

The syringe plunger back force is calibrated in kgf (at 0.0kgf and 4.0kgf). The implied line pressure in the syringe is calculated in the pump based on typical samples of the syringe types specified for use with the device.

APPENDIX G - BOLUS VOLUME ACCURACY

The following table provides an indication of the accuracy with which a bolus infusion will be delivered. Test carried out as specified in IEC601-2.

BOLUS VOLUME (ml)	BOLUS RATE (ml/hr)	NO. OF SAMPLES	MAX. POSITIVE (%)	MAX. NEGATIVE (%)	MEAN (ml)
0.1	100	25	+12.0	-14.0	-5.0
2.0	100	25	+2.5	-0.0	+1.0
5.0	100	25	+1.0	-0.0	+0.8

APPENDIX H - PCAM PRINTER INTERFACE

PCAM pumps are fitted with an interface which can be used to connect a printer, computer, respiration monitor or a nurse call system. The printer interface is described in detail in this section. The printer interface is serial RS232 port comprising pins 5, 8 and 9 on the PCAM 9 pin interface connector. Note that this interface is independent from the computer communications interface which may be an RS232 or RS485 port.

The printer connected to the PCAM needs to meet the specification set out below. Since many PC compatible printers have multi-pin parallel ports it is possible to use these with a suitable serial to parallel converter plugged into the printer; a specification for such a converter is also included. One suitable printer for use with the PCAM is the 'CITIZEN PN60' for which a special cable is available from IVAC.

The printer protocol uses standard ASCII characters along with EPSON emulation control codes and graphics characters. Inability to set EPSON emulation may result in text not lined up correctly on the printed page, and the history graphs not being printed correctly.

PCAM INTERFACE PIN-OUT		
PCAM 9-PIN INTERFACE	PIN NUMBER	PRINTER CONNECTIONS
ALM INPUT (active low)	1	-
RXD2/data+	2	-
TXD2/data-	3	-
PWR1 (+10V)	4	-
GND	5	Ground
RXD1	6	-
RTS1	7	-
CTS1	8	Printer on-line / buffer not full (DTR)
TXD1	9	Data to printer

Suitable printers include the Citizen PN60 and the Canon BJ-10sx (with serial to parallel converter RS Components RS201-742).

PRINTER SPECIFICATION	
PRINTER FEATURE	SETTING
EMULATION	EPSON (FX-85, LQ-510 or similar)
LINE SPACING	6 lines per inch
PAPER	A4
AUTO	Automatic line feed off
BAUD RATE	9600 baud, 8 data bits, 1 stop bit, no parity
PROTOCOL	CTS/DTR (not XON/XOFF)

APPENDIX H - PCAM PRINTER INTERFACE (continued)

Citizen PN60 users note: suitable printer default settings are: language - English; emulation - Epson; print style - Roman, 12 cpi, font lock off; page layout - compress off, 6 lpi, A4, mirror off; character set - slash off, graphics, U.K., code page U.S.A.; install 2 - auto linefeed off, space skip disable, power off 3 min; serial interface - auto, 9600, DTR.

Canon BJ-10sx users note: printer bit switch settings to select Epson emulation, auto line feed off, page length to A4 and character set to UK - set from left (1) to right (11) - OFF, OFF, OFF, ON, ON, OFF, OFF, ON, OFF, OFF, ON.

OPTIONAL SERIAL TO PARALLEL CONVERTER SPECIFICATION	
SERIAL TO PARALLEL CONVERTER	SPECIFICATION
PRINTER CONNECTION	36 way Centronics - Parallel
SERIAL CONNECTION	25 pin D type female
BAUD RATE	9600 baud, 8 data, 1 stop bit, no parity
HANDSHAKING	Hardware CTS/DTR (not XON/XOFF)
TERMINAL SETTING	DTE
POWER	External power

Suitable serial to parallel converters include the RS Components RS201-742.

IVAC PCAM PRINTER ACCESSORIES	
5000SP00008	PCAM Printer Cable. 9 To 25 Pin (9-pin female (PCAM) to 25-pin male (printer))
5000SP00011	PCAM Citizen PN60 Printer Cable. 9-pin female (PCAM) to 26 pin AMP 17823404

PCAM PRINTER CABLE WIRING DIAGRAMS

Wiring information below indicates pin numbering for printer cables:

9 PIN PCAM TO 25 PIN SERIAL PRINTER (IVAC REF: 5000SP00008)		
PCAM		PRINTER
Pin 5 (Ground)	----------	Pin 7 (Ground)
Pin 8 (CTS)	----------	Pin 20 (DTR - printer on-line)
Pin 9 (Tx)	----------	Pin 3 (Rx)

CITIZEN PN60 9 PIN PCAM TO 26 PIN AMPHENOL CON. (IVAC REF: 5000SP00010)		
PCAM		PRINTER
Pin 5 (Ground)	----------	Pins 1 & 2 (Ground)
Pin 8 (CTS)	----------	Pin 18 (DTR - printer on-line)
Pin 9 (Tx)	----------	Pin 15 (Rxd-)

9 PIN PCAM TO 9 PIN SERIAL PRINTER (NOT AVAILABLE AS A STANDARD PART)		
PCAM		PRINTER
Pin 5 (Ground)	----------	Pin 5 (Ground)
Pin 8 (CTS)	----------	Pin 4 (DTR - printer on-line)
Pin 9 (Tx)	----------	Pin 2 (Rx)

APPENDIX I - PCAM COMPUTER COMMUNICATIONS INTERFACE

1. INTRODUCTION

PCAM pumps are fitted with an interface used to connect the PCAM to a printer, a computer, a respiration monitor or a nurse call system. The general computer communications interface is described in detail in this section. Two forms of communication standard are available in the hardware of the PCAM: pumps are fitted with either an RS232 or RS485 comms interface. Note that this interface is independent from the printer interface which is always an RS232 port.

IVAC supply communications demonstration software on request which operates under MS Windows and demonstrates data retrieval from a PCAM connected to a computer.

2. WHY USE A COMMUNICATIONS INTERFACE?

It is becoming more common to have a computer at the bedside in certain intensive care environments. This is used to assimilate and record data from a number of medical devices, as well as from text typed at a keyboard. The computer may then be linked to a network allowing patient information to be available across the entire network. The local computer can collect data from the PCAM using the communications interface, and then process this data to form useful information regarding the infusion.

Most personal computers are fitted with at least one RS232 serial port (either 9 pin or 25 pin). Clinical bedside monitoring and central monitoring stations also commonly include RS232 interfaces to talk to devices being used at the bedside. A newer development of bedside monitoring involves the use of RS485 interfaces as an alternative to RS232.

3. DATA RETRIEVAL FROM THE PCAM

The computer communications interface allows information in the PCAM to be monitored from a computer as often as required. The communication takes the form of a message request passed from the computer to the PCAM which then replies with an information set containing the requested data. The PCAM transmits data whenever requests are made provided the PCAM identity is correctly included in the request message.

Where RS232 is a point to point system, with a single cable connecting a device such as the PCAM to a computer, RS485 allows many devices to be connected to the same cable with one computer port also connected. In RS485 an identity number is included in each message sent by the master computer out to the attached devices. The identity numbers set must be unique to one device on the connection (also called a 'bus') and this device only responds with data requested by the master computer.

PCAM protocols are set up to include an identity number whether the protocol in use is RS232 or RS485. A PCAM will only respond to a message requesting data in the event that the request identity matches the PCAM identity, in the range '0' to '127' (or in the event that the identity used is the all inclusive broadcast identity number, '254').

4. CONTROL OF PCAM

Given the nature of PCAM as a Patient Controlled Analgesia device there is no control mode available in the PCAM communications protocol.

5. CONFIGURATION OF PCAM

PCAM can be configured with a wide range of parameters including certain drug related safety limits, drug names, pre-set protocols and other general options. The communications interface allows the programming of these configuration parameters in a special PCAM access code, known as 'learn' mode. A computer can be set to program the configuration of a PCAM device using this mode. In addition to 'learn' mode there is another access code which sets 'teach' mode. This allows one PCAM to be used to program another. Note: a PCAM device with an RS485 interface cannot be programmed from a computer with an RS232 interface - only matched interfaces can be used.

APPENDIX I - COMMUNICATIONS INTERFACE (continued)

6. TEACH / LEARN MODE

By programming the configuration of one PCAM in the conventional way from the front panel buttons other PCAM devices can have the configuration copied over using the 'teach' and 'learn' modes.

When set to 'learn' mode the PCAM will accept information sets from a pre-configured PCAM set to 'teach' mode.

When set to 'teach' mode the PCAM sends out via the communications interface a sequence of all the information sets required to configure another PCAM device. To fully configure a unit it is necessary to send 12 complete information sets as described in the protocols and the full cycle takes about 15 seconds.

The two PCAM's must be connected together using an RS232 Demonstration Cable Both PCAM's must be of the same version software and revision (see appendix A -self test routine) and set to a common pump comms identity number (see general options). The configured PCAM is set to 'teach' mode and the device to be configured is set to 'learn' mode using the access codes below. The PCAM in 'learn' mode will display the information set being received from the 'teach' mode device.

The devices must run through at least one complete sequence of the information sets and then switch off first the 'learn' pump and then the 'teach' pump. After using this method it is the users responsibility to check that the configuration has been copied over correctly.

MODE	POWER UP ACCESS CODE
LEARN mode	**167**
TEACH mode	**168**

APPENDIX J - CONFIGURATION RECORD

Use the following sheets to record the configuration settings and default **PCAM** protocols.

CONFIGURATION RECORD			PCAM SERIAL NO:	5001-
1	Icons		YES - Display icons. NO - Icons off.
2	Protocols in use		1 to 5 protocols.
3	Modify protocol		YES to allow modify in SET. NO to disable.
4	Handset Mode		A, B or C.
5	Delayed Callback		YES - callback alarm after 2 mins. NO - no callback alarm.
6	Display Sleep		YES - display blank after 2 mins. NO - display stays on.
7	Chirp low alarms		YES - "chirp" alarm. NO - no "chirp" alarm.
8	Continuous infusions		YES - Continuous infusions. NO - Disabled.
9	Loading doses		YES - Loading dose available. NO - Disabled.
10	Max dose limits		YES - Dose limits available. NO - Disabled.
11	Variable dose rates		YES - Variable rates available. NO - Disabled.
12	Comms pump identity		Use arrows to set pump identity in range "1" to "127". Default setting is "0 0 0".
13	Comms enabled		YES - Communications enabled. NO - Communications disabled.
14	Nurse call		YES - Nurse call connector enabled. NO - Nurse call connector disabled.
15	Continuous Print		YES - Continuous printed enabled. NO - Continuous print disabled.
16	Default syringe		
17	Lock syringe type		

DRUG	NAME	MIN CONC	MAX CONC	MIN DOSE	MAX DOSE
DRUG 1					
DRUG 2					
DRUG 3					
DRUG 4					
DRUG 5					

APPENDIX J - CONFIGURATION RECORD

Use the following sheets to record the configuration settings and default **PCAM** protocols.

A	PROTOCOL SUMMARY		
1	DRUG NAME		up to 10 letters
2	DRUG CONC.		ug/ml or mg/ml
3	PCA DOSE		ug or mg
4	LOCKOUT PERIOD		minutes
5	OCCLUSION LEVEL		Level 0 to 10
6	CONTINUOUS RATE		ug/h or mg/h
7	LOADING DOSE		ug or mg
8	MAX DOSE LIMIT		ug or mg
9	DOSE LIMIT DURATION		1 to 8 hours
10	PCA DELIVERY PERIOD		STAT or 1 to 60 mins.
	CONFIGURED BY:		DATE:

B	PROTOCOL SUMMARY		
1	DRUG NAME		up to 10 letters
2	DRUG CONC.		ug/ml or mg/ml
3	PCA DOSE		ug or mg
4	LOCKOUT PERIOD		minutes
5	OCCLUSION LEVEL		Level 0 to 10
6	CONTINUOUS RATE		ug/h or mg/h
7	LOADING DOSE		ug or mg
8	MAX DOSE LIMIT		ug or mg
9	DOSE LIMIT DURATION		1 to 8 hours
10	PCA DELIVERY PERIOD		STAT or 1 to 60 mins.
	CONFIGURED BY:		DATE:

C	PROTOCOL SUMMARY		
1	DRUG NAME		up to 10 letters
2	DRUG CONC.		ug/ml or mg/ml
3	PCA DOSE		ug or mg
4	LOCKOUT PERIOD		minutes
5	OCCLUSION LEVEL		Level 0 to 10
6	CONTINUOUS RATE		ug/h or mg/h
7	LOADING DOSE		ug or mg
8	MAX DOSE LIMIT		ug or mg
9	DOSE LIMIT DURATION		1 to 8 hours
10	PCA DELIVERY PERIOD		STAT or 1 to 60 mins.
	CONFIGURED BY:		DATE:

APPENDIX J - CONFIGURATION RECORD

Use the following sheets to record the configuration settings and default **PCAM** protocols.

D	PROTOCOL SUMMARY		
1	DRUG NAME		up to 10 letters
2	DRUG CONC.		ug/ml or mg/ml
3	PCA DOSE		ug or mg
4	LOCKOUT PERIOD		minutes
5	OCCLUSION LEVEL		Level 0 to 10
6	CONTINUOUS RATE		ug/h or mg/h
7	LOADING DOSE		ug or mg
8	MAX DOSE LIMIT		ug or mg
9	DOSE LIMIT DURATION		1 to 8 hours
10	PCA DELIVERY PERIOD		STAT or 1 to 60 mins.
	CONFIGURED BY:		DATE:

E	PROTOCOL SUMMARY		
1	DRUG NAME		up to 10 letters
2	DRUG CONC.		ug/ml or mg/ml
3	PCA DOSE		ug or mg
4	LOCKOUT PERIOD		minutes
5	OCCLUSION LEVEL		Level 0 to 10
6	CONTINUOUS RATE		ug/h or mg/h
7	LOADING DOSE		ug or mg
8	MAX DOSE LIMIT		ug or mg
9	DOSE LIMIT DURATION		1 to 8 hours
10	PCA DELIVERY PERIOD		STAT or 1 to 60 mins.
	CONFIGURED BY:		DATE:

	PROTOCOL SUMMARY		
1	DRUG NAME		up to 10 letters
2	DRUG CONC.		ug/ml or mg/ml
3	PCA DOSE		ug or mg
4	LOCKOUT PERIOD		minutes
5	OCCLUSION LEVEL		Level 0 to 10
6	CONTINUOUS RATE		ug/h or mg/h
7	LOADING DOSE		ug or mg
8	MAX DOSE LIMIT		ug or mg
9	DOSE LIMIT DURATION		1 to 8 hours
10	PCA DELIVERY PERIOD		STAT or 1 to 60 mins.
	CONFIGURED BY:		DATE:

APPENDIX K - SERVICE CONTACTS

For service contact your local IVAC Affiliate Office or Distributor.

IVAC Service Centre Addresses :

Belgium

IVAC Medical B.V., Belgian Branch
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APPENDIX K - SERVICE CONTACTS (continued)

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RG24 0NE
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Fax : (44) 1256 463770

APPENDIX L - WARRANTY

IVAC Medical Systems (hereinafter referred to as "IVAC") warrants that:

(A) Each new instrument (pump, controller or peripheral instrument) is free from defects in material and workmanship under normal use and service for a period of one year from the date of delivery by IVAC to the first purchaser.
(B) Each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by IVAC to the first purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local IVAC centre to determine appropriate repair facility. Repair or replacement will be carried out at IVAC's expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to IVAC shall be at purchaser's risk.

In no event shall IVAC be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any IVAC product. This warranty shall not apply to, and IVAC shall not be responsible for, any loss arising in connection with the purchase or use of any IVAC product which has been repaired by anyone other than an authorised IVAC service representative or altered in any way so as, in IVAC's judgement, to affect its stability or reliability, or which has been subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed, or which has been used otherwise than in accordance with the instructions furnished by IVAC.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations of liabilities on IVAC's part, and IVAC neither assumes nor authorises any representative or other person to assume for it any other liability in connection with the sale of IVAC products. See packing inserts for international warranty.

IVAC DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

APPENDIX M - NOTES AND AMENDMENTS

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Spares Kit Case Upper V4

This instruction applies only to **IVAC** 'P' Series Syringe Pumps.

Ensure the unit is disconnected from AC power supply and switched off before attempting to service the unit.

This equipment contains static sensitive components. Observe strict precautions for the protection of the static sensitive components when attempting to repair and service the equipment.

Ensure all the test calibration procedures are carried out as recommended in the technical service manual after any component fitting.

For further information refer to final assembly drawing no. 1001PP00003 and relevant component replacement sections as detailed in the service manual, publication numbers 1000PB00048 when following this instruction.

Ensure that no undue force is applied to the plunger holder and the leadscrew, when the unit is placed upside down to remove the six case retaining screws (M4 x 45mm pan head) on the base.

Always protect the plunger holder and leadscrew by spacing the front face of the pump off the work service when the pump is upside down. A 50ml syringe placed in the syringe clamp may be used if necessary, but for regular servicing we recommend the use of the upper case support cradle Part No. 0000JG00004.

1.0 Introduction

This fitting instruction applies to the replacement of the V4 style upper case. To replace the upper case it will be necessary to gain access to the inside of the Syringe Pump.

Important before fitting the new upper case it will be necessary to purchase a new front panel label, see table overleaf for part number and type :

PART NUMBER	DESCRIPTION
1000LB00032	LABEL FRONT PANEL IVAC P1000 ENGLISH
1000LB00040	LABEL FRONT PANEL IVAC P1000 DUTCH
1000LB00047	LABEL FRONT PANEL IVAC P100 FRENCH
1000LB00055	LABEL FRONT PANEL IVAC P1000 GERMAN
1000LB00066	LABEL FRONT PANEL IVAC P1000 SPANISH
1000LB00088	LABEL FRONT PANEL IVAC P1000 SWEDISH
2000LB00019	LABEL FRONT PANEL IVAC P2000 ENGLISH
2000LB00025	LABEL FRONT PANEL IVAC P2000 DUTCH
2000LB00031	LABEL FRONT PANEL IVAC P200 FRENCH
2000LB00037	LABEL FRONT PANEL IVAC P2000 GERMAN
2000LB00054	LABEL FRONT PANEL IVAC P2000 SWEDISH
3000LB00005	LABEL FRONT PANEL IVAC P3000 ENGLISH
3000LB00006	LABEL FRONT PANEL IVAC P3000 DUTCH
3000LB00007	LABEL FRONT PANEL IVAC P300 FRENCH
3000LB00008	LABEL FRONT PANEL IVAC P3000 GERMAN
3000LB00009	LABEL FRONT PANEL IVAC P3000 SPANISH
3000LB00013	LABEL FRONT PANEL IVAC P3000 SWEDISH
4000LB00002	LABEL FRONT PANEL IVAC P4000 ENGLISH
4000LB00003	LABEL FRONT PANEL IVAC P4000 DUTCH
4000LB00004	LABEL FRONT PANEL IVAC P400 FRENCH
4000LB00005	LABEL FRONT PANEL IVAC P4000 GERMAN
4000LB00006	LABEL FRONT PANEL IVAC P4000 SPANISH
4000LB00009	LABEL FRONT PANEL IVAC P4000 SWEDISH

2.0 Access to the Pump

2.1 Place the unit on a static dissipative surface that is correctly grounded.

2.2 Remove the six case retaining screws (M4 x 45mm pan head) located on the base of the unit.

2.3 Carefully separate the upper and lower case halves and disconnect the grey ribbon cable from the socket on the power supply and RS232 cables if fitted.

3.0 Fitting Instructions

3.1 Carefully remove the syringe type label from the existing upper case and transfer it to the new upper case.
Fit the serial label (supplied) to the new upper case and copy across the number from the old upper case.

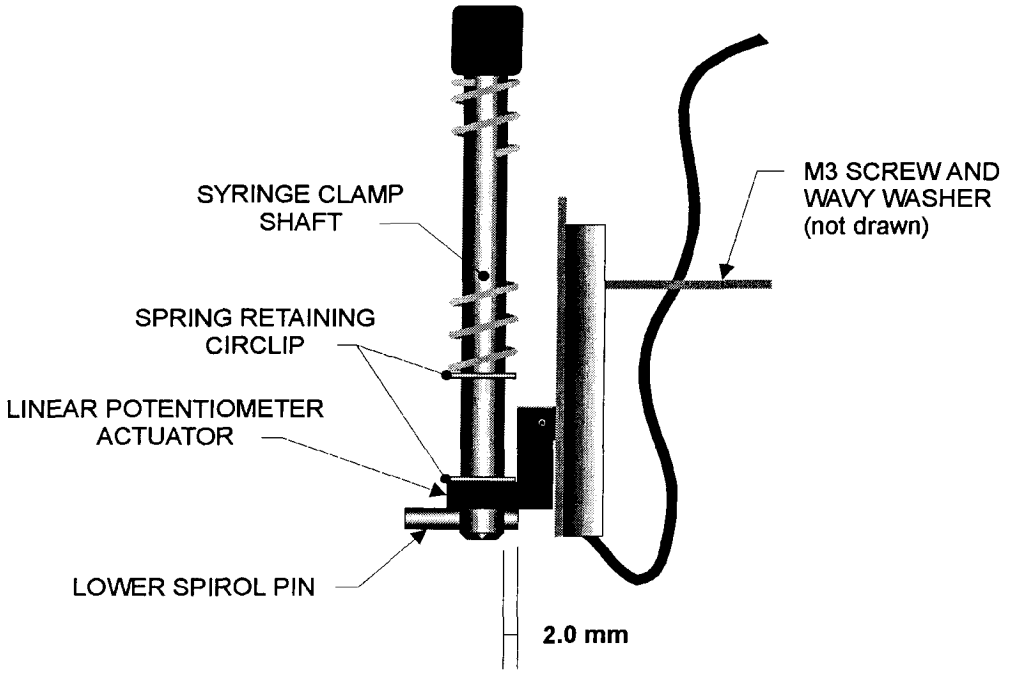
3.2 Carefully remove the transmission flexible circuit connector, strain gauge beam connector, linear potentiometer connector and shielding cable.

3.3 Remove the six PCB fixing screws and withdraw both the control and display PCB's together. The two PCB's are linked by a turned pin connector.
Fitted over the buttons on the control panel are spacers, ensure these are still in position and are not still in the recesses of the old upper case.
Fit the PCB's into the new upper case taking care not to disturb the spacers. Secure using the six screws removed earlier.

3.4 Remove the three M4 screws and washers securing the transmission chassis plate to the upper case, then remove the two M4 countersunk screws from the beam. Lift the transmission assembly out of the upper case. Do not refit.

3.5 Remove the lower spirol pin which retains the linear potentiometer actuator. Undo the M3 screw which retains the potentiometer mounting bracket and slide the actuator off the syringe clamp shaft, removing the assembly from the case half.
Carefully prise the spring retaining circlips (2 off) from the shaft and remove the shaft and spring. Refit into the new upper case.
Now slide the actuator over the shaft and refit the diameter 3.0mm x 16mm long spirol pin, such that the pin is orientated to slide in the groove in the lower case. 2mm should protrude through the other side of the shaft to aid in the location and support of the actuator.

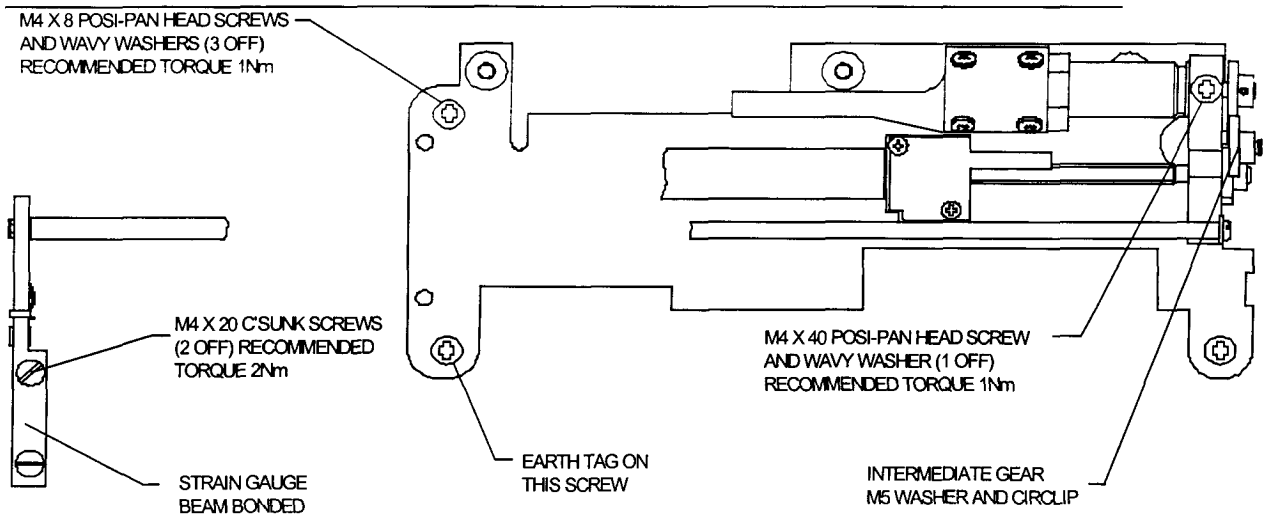
3.6 Fit the silicone cord (1000ME01087) into the groove in the upper case. The join of the silicone cord is to be fitted in the same position as the old case. Ensure that the cord is not stretched as it is fitted as this will impair the cords ability to seal the join between the two cases when the unit is fully assembled.



POTENTIOMETER ACTUATOR ASSEMBLY

3.7 Refit the M3 screw and wavy washer to secure the potentiometer mounting bracket. Before tightening the screw fully check the potentiometer is fitted parallel to the syringe clamp shaft subtly bending the bracket if necessary.
Tighten the screw fully and check that the shaft, potentiometer actuator and slider operate freely.

3.8 Replace the transmission assembly into the new upper case, ensuring that the torsion rod is correctly located in the torsion rod bracket and that both the outer tube and leadscrew seals are correctly located in their respective positions in the case.
Screw down the transmission at the beam end and chassis plate using the M4 screws and washers removed earlier on the chassis plate and the two countersunk screws on the beam end and also the earth tag.
Check that the leadscrew gear does not touch the upper case wall and that a minimum gap of 1mm exists between the back face of the gear and the front face of the motor bearing plate. The clearance is dependant upon the fixing position of the strain gauge beam. Refit the idler and circlip.
Remove the middle idler gear on the motor mounting plate. Check the leadscrew rotates smoothly and both the outer tube seal and leadscrew seal are free to rotate without binding. If there is resistance or a tight spot it will be necessary to remove the transmission and investigate this.



PART VIEW OF THE TRANSMISSION ASSEMBLY

3.9 Confirm that the declutch microswitch actuates before the transmission can be disengaged and the transmission can be moved freely along the leadscrew.
If the movement is restricted it will be necessary to readjust the two screws securing the microswitch mounting plate to the carriage.

3.10 Refit the transmission flexible connector, strain gauge beam connector, linear potentiometer connector and shielding cable back to the control PCB. This needs to be done when transmission is fitted.

3.11 Reconnect the upper and lower case halves ensuring the grey ribbon cable is reconnected to the control PCB and the RS232 cables (if fitted) are reconnected.
Before screwing the unit back together it is advisable to carry out the self test routine as described in the technical service manual. Functionally check the operation and sensitivity of the various front panel buttons. Secure the two case halves using the M4 x 45mm long screws and washers.

3.12 Repeat the self test routine and confirm the occlusion and linear speed calibration. Functional testing may also be advisable prior to returning the unit back into service.

4.0 Technical Inquiries.

For additional technical assistance, contact your local ALARIS Service Operations.